Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

1-89

K141619

Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FDA CDRH DMC
JUN 17 2014
Received

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table of Content:

Section Number	Content
Section 1	Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2	CDRH Premarket Review Submission Cover Sheet
Section 3	510(k) Cover Letter
Section 4	Indications for Use Statement
Section 5	510(k) Summary
Section 6	Truthful and Accuracy Statement
Section 7	Class III Summary and Certification
Section 8	Financial Certification or Disclosure Statement
Section 9	Declarations of Conformity and Summary Reports
Section 10	Executive Summary
Section 11	Device Description
Section 12	Substantial Equivalence Discussion
Section 13	Proposed Labeling
Section 14	Sterilization and Shelf Life
Section 15	Biocompatibility
Section 16	Software
Section 17	Electromagnetic Compatibility and Electrical Safety
Section 18	Performance Testing – Bench
Section 19	Performance Testing – Animal
Section 20	Performance Testing – Clinical
Attachment 1	Form 3654s
Attachment 2	Form 3674
Appendix 1	Test Reports
Appendix 2	DMF Authorization Letters

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

HUIZHOU FORYOU MEDICAL DEVICES CO LTD
North Shangxia Road, Dongjiang Hi-tech Industry Park
HUIZHOU
China
Guangdong
516005
CN

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Jin Tuan Lin
2.1 E-MAIL ADDRESS
jtlin@foryougroup.com
2.2 TELEPHONE NUMBER (include Area code)
+86-0752 5302031
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
+86-0752 5302020

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
30-May-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/05/2014		

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*
HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD	3007735241
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	(086)0752-5302188
Street Address	**FAX Number *(including area code)***
No.1 Shangxia North Road, DONGJIANG HI-TECH INDUSTRIAL PARK	(086)0752-5302020

City	State / Province	ZIP/Postal Code	Country
Huizhou	Guangdong	516005	China

Contact Name	
Charles Shen	
Contact Title	**Contact E-mail Address**
Regulatory Correspondent	cyshen@aol.com

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	
MANTON BUSINESS AND TECHNOLOGY SERVICES	
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	001-608-217-9358
Street Address	**FAX Number *(including area code)***
853 Dorchester LN, Unit-B	001-425-930-2155

City	State / Province	ZIP Code	Country
New Milford	NJ	07646	USA

Contact Name	
Charles Shen	
Contact Title	**Contact E-mail Address**
N/A	cyshen@aol.com

PSC Publishing Services (301) 443-6740 EF

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K110062	MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFo	MediPurpose, Pte. Ltd
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Luofucon Silver Foam Dressing

	Trade or Proprietary or Model Name for This Device	Model Number
1	Luofucon Silver Foam Dressing	Various
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1		2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FRO

C.F.R. Section *(if applicable)*: N/A

Device Class

- [ ] Class I
- [ ] Class II
- [ ] Class III
- [x] Unclassified

Classification Panel

general & plastic surgery

Indications *(from labeling)*

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
Ulcers (venous, arterial, diabetic) Pressure Sores Donor Sites Surgical Incisions Surgical Excisions Burns (1st and 2nd degree)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: 3007735241

☒ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD	3007735241
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	(086)0752-5302188
Street Address	**FAX Number *(including area code)***
No.1 Shangxia North Road, DONGJIANG HI-TECH INDUSTRIAL PARK	(086)0752-5302020

City	State / Province	ZIP Code	Country
Huizhou	Guangdong	516005	China

Contact Name	Contact Title	Contact E-mail Address
Charles Shen	Regulatory Correspondent	cyshen@aol.com

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
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Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO-10993-5	ISO	Biological Evaluation of medical Devices. Part 5- Tests for in Vitro Cytotoxieity	2009	7/31/2009
2	ISO-10993-10	ISO	Biological Evaluation of medical Devices. Part 10- Tests for irritation and Delayed Type Hypersensitivity	2010	12/31/2010
3	ISO-10993-11	ISO	Biological Evaluation of medical Devices. Part 11- Tests for Systematic Toxieity	2009	8/30/2009
4	ISO-11135-1	ISO	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization	2007	05/01/2007
5	USP 34<731>	USP	Loss on Drying	34	11/1/2010
6	USP 34<791>	USP	pH	34	01/07/2012
7	AATCC-100	AATCC	Antibacterial Finishes on Texitic Materials. Assessment of	2004(R2008)	6/30/2008

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 4: Indication for Use Statement

510(k) Number (if known):

Device Name: Luofucon Silver Foam Dressing

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing layer is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof and semi permeable. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

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Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 6: Truthful and Accuracy Statement

Premarket Notification

Truthful and Accuracy Statement

for

Luofucon Silver Foam Dressing

I certify that, in my capacity as President of *Huizhou Foryou Medical Devices Co., Ltd.* believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Luofucon Silver Foam Dressing are truthful and accurate and that no material fact has been omitted.

Signature, Jinwen Mo

6/12/2014

Date

General Manager

Huizhou Foryou Medical Devices Co., Ltd.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7: Class III Summary and Certification

This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 8: Financial Certification or Disclosure Statement

This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9: Declarations of Conformity and Summary Reports

Our Submission is traditional 510(k). This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Executive Summary

This section composes the following:

- Section 10.1: Concise description of the device, including the indications for use and technology;
- Section 10.2: Device Comparison
- Section 10.3: Concise Summary for Performance Testing

Section 10.1: Concise Description of the Device (including the indications for use and technology)

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane foam and silver particles, which absorbs wound exudate and releases silver in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane foam material consists of metallic silver that provides effective protection of the dressing against microbial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days period, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The product in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, of the silver foam dressing has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer (non-wound contacting) side of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing as the adhesive to secure the dressing on patient skin surface. The film backing is waterproof and semi permeable. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing as the adhesive to secure the dressing on patient skin surface. The film backing is waterproof. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Section 10.2 Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 10.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes

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Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has both single layered and double layered structure. This small difference does not impact the safety and efficacy of the two devices.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 10.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 10.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six

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(three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for four days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Section 10.3 Concise Summary for Performance Testing

The following Biocompatibility testing results are included in **Section 15** of this submission.

Purpose	Testing Standard
Cytotoxicity	ISO10993-5
Skin Irritation and Sensitization	ISO 10993-10
Systematic Toxicity	ISO 10993-11

The results show all materials are not cytotoxic, do not cause skin irritation, and sensitization, and have no systematic toxicity.

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The following bench performance testing results are included in **Section 18** of this submission for a representative lot.

Test items	Specification	Test Results	Test Method
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform	Visual
Dimension	Deviation ≤ ±5%	Conform	Calibrated ruler
Density	0.09-0.18 g/cm^3	0.110gram/m^3	Internal Method
Free Swell Absorption	≥10.0 g/g	13.8 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	4.98%	USP 34 <731> Loss on drying
pH	4.0～9.0	4.73	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	2.85 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria	AATCC 100: 2004

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we tested three (3) gram positive bacteria and three (3) gram negative bacteria, for the evaluation of broad spectrum antibacterial effectiveness of the silver foam dressing. The dressings are effective (>99.99% reduction) toward all six bacteria for three days.

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Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 8
11.4 Test Results 9
11.5 List of All Materials Used 10
11.6 Manufacturing Process 11
11.7 Silver Compound Used in the Products and Silver Particle Size 13
11.8 Bonding Between Silver Particles and Silver Leachability 14
11.9 Antimicrobial Activity Spectrum (Profile) 17
11.10 Minimum Effective Concentration 17
11.11 Likely Silver Antibacterial Mechanism 18

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11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2).

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A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing layer is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof and semi permeable. The product line is available in different sizes (See Table 11.3).

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof. The product line is available in different sizes (See Table 11.4).

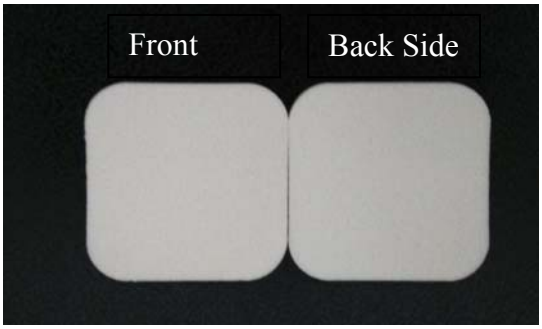
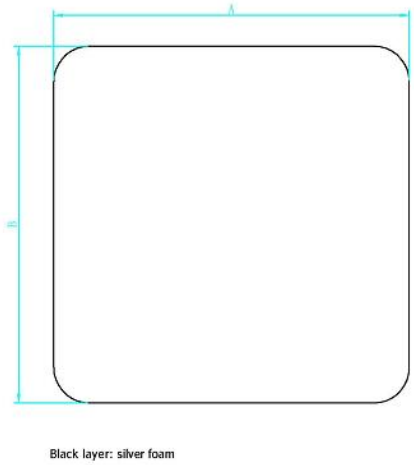
The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

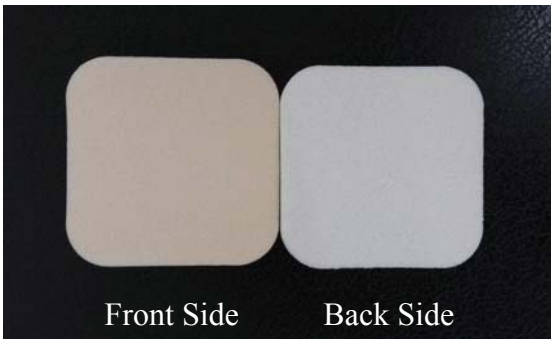
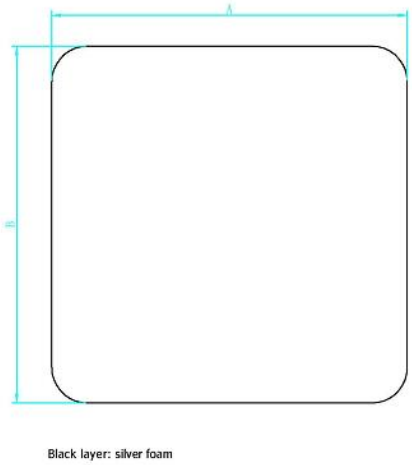
Representative Picture	**Drawing**
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

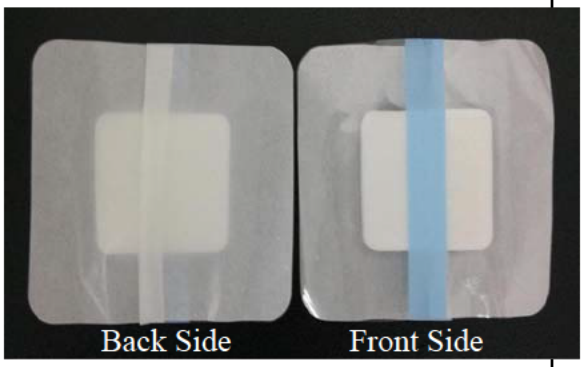
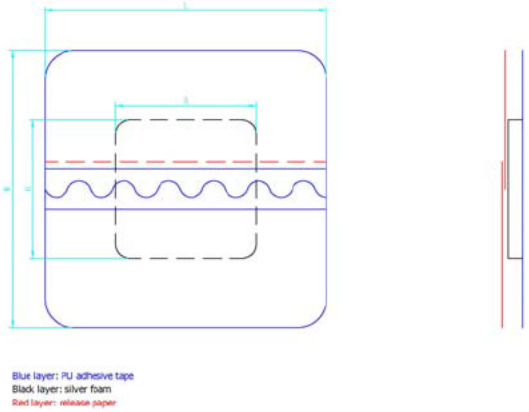
Representative Picture	**Drawing**
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

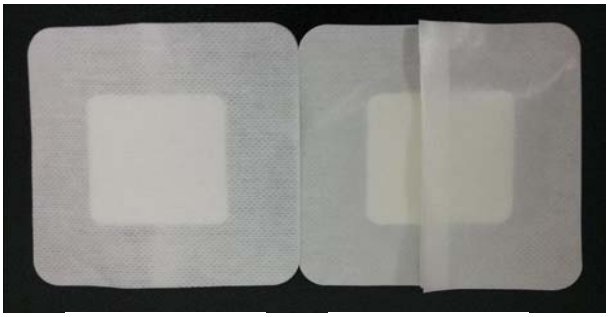
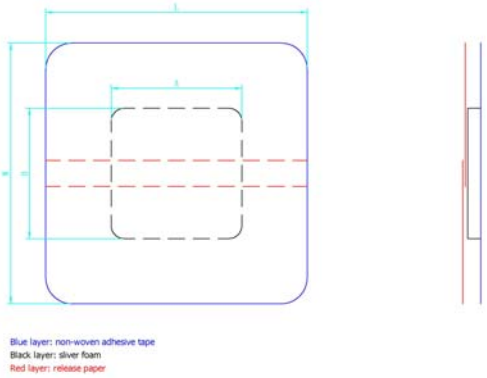
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	**Drawing** [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Packaging information is listed below:

Immediate Packaging:
Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging:

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Paper Box
Outer Packaging:
Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.5. The biological specifications are shown in Table 11.6.

Table 11.5: Physical Specification of Luofucon Silver Foam Dressing

Test items	**Specification**	**Test Method** [a]
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation $\leq \pm 5\%$	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying
pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]**:** Details are described in *Section 18: Performance Testing: Bench*

The biological specifications are shown in Table 11.6.

Table 11.6 Biological Specifications

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

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11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201305001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.5 and 11.6.

Table 11.5: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201305001, size 100 mm x 100 mm x 3 mm)

Test items	Specification	Test Results
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5%	Conform
Density	0.09-0.18 g/cm^3	0.110 gram/m^3
Free Swell Absorption	≥10.0 g/g	13.8 g/g
Loss on Drying	≤6%	4.98%
pH	4.0～9.0	4.73
Silver Content [a]	3±1 μg/cm^3	2.85 μg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

(b) (4)

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Table 11.6: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

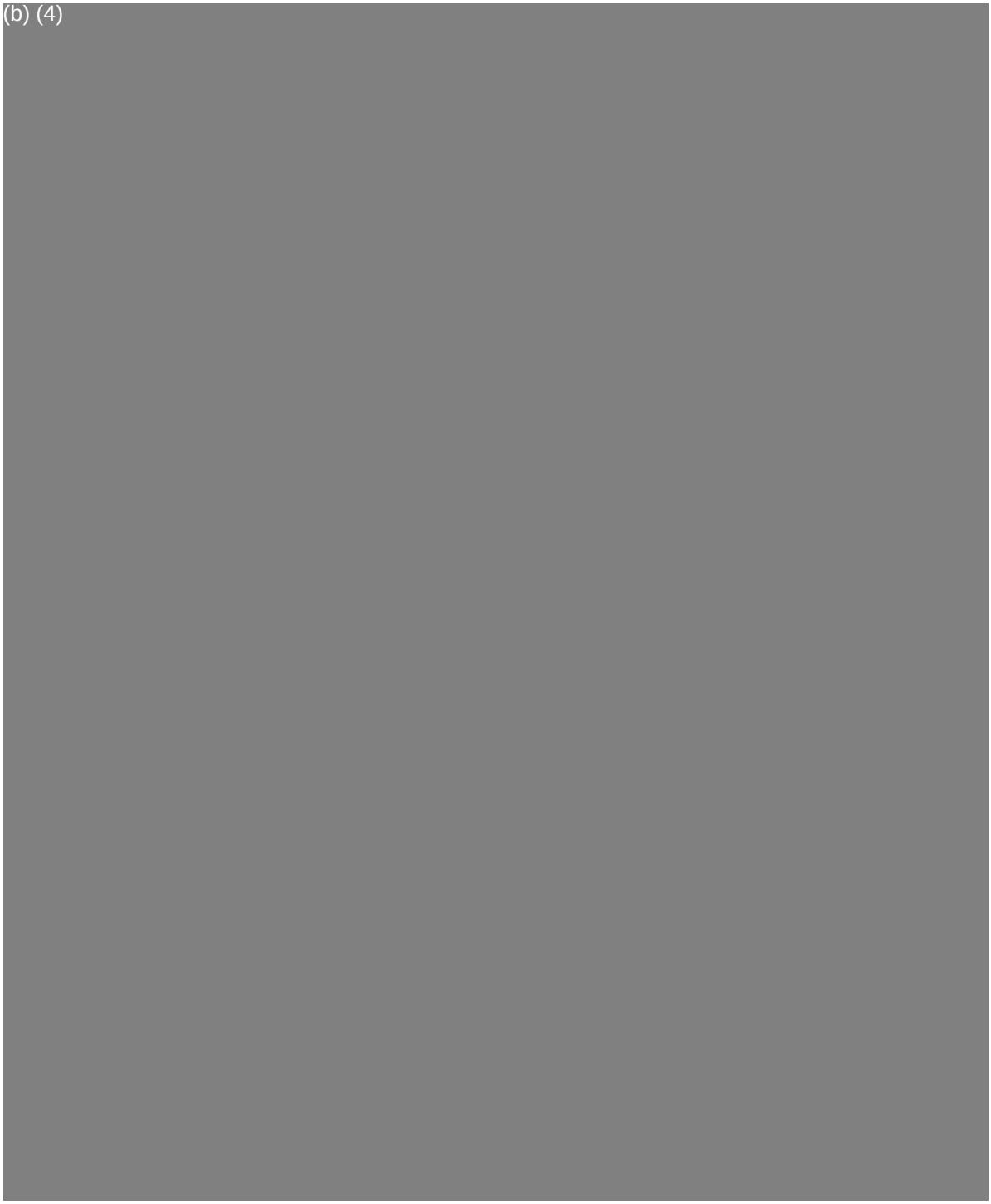
(b) (4)

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11.6 Manufacturing Process

(b) (4)



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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. One piece of silver dressing in the size of 100 x 100 x 3 mm were used and immersed in 20 mL of simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, 48, and 72 hours
Extraction temperature: 25 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry).

The test results are summarized in the Table 11.10 below. % of Total Silver is calculated using a nominal silver amount of 3 μg/cm^3 (total silver is 90 μg for 100 x 100 x 3 mm dressing)

The leachables are calculated as both daily leachable, which is the leached silver amount with 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

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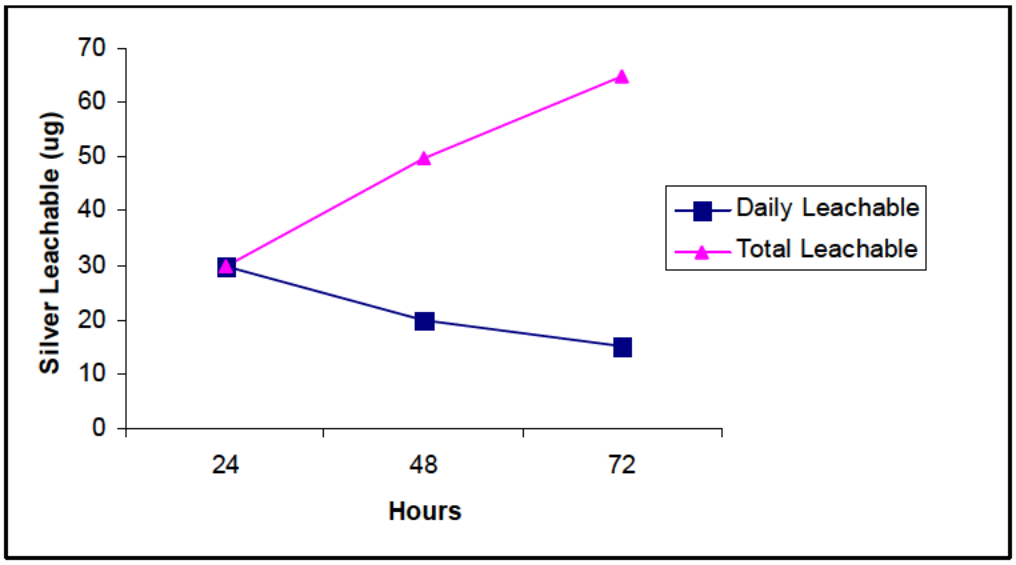
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Table 11.10: Silver Dressing Leachable Study. Test conditions are discussed above.

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Leachable (µg)	Daily leachable as % of Total Silver[a]	Total Leachable (µg)	Total Leachable as % of Total Silver[a]
24	1.50	20	30.0	33.3%	30.0	33.3%
48	0.99	20	19.8	22.0%	49.8	55.3%
72	0.75	20	15.0	16.7%	64.8	72.0%

[a]: 100 x 100 x 3 mm foam contains 90 µg silver, and was used in the calculation

Under this simulated condition, Luofucon Silver Foam Dressing leaches about 33.3% of the total silver during the first 24 hours, and leaches about 22.0%, and 16.7% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours about 72.0% of the total silver was leached out. This is also presented in the plot below:



This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

Since the nominal concentration of silver is 3±1 µg/ cm^3, after three days of recommended usage duration, at least 72.0% of silver is released, equivalent to at least 2.2 µg/cm^3. This number (2.2 µg/cm^3) will be shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, therefore causing much less skin discoloration effect.

Details of this experiment can be found in **Section 18**

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11.9 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.10 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.11 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 12: Substantial Equivalence Discussion

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

Table 12.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same

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Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 12.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 12.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and

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sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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Section 13: Proposed Labeling

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 6

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

RX Only
version: A/0

Product Name
LUOFUCON® Silver Foam Dressing

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment to accelerate healing process. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. LUOFUCON® Silver Foam Dressing can restrain the bacteria growing and reduce infection. LUOFUCON® Silver Foam Dressing has been tested *in vitro* and found to be effective against bacteria such as Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonsa aeruginosa and Klebsiella pneumoniae.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers (venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns (1st and 2nd degree)

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

Product Information:

Antibacterial Agent:	Silver particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 2-4ug/cm^3 silver

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity till day-3. The device has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Bacterial	Staphylococcus aureus ATCC 6538	Streptococcus pyogenes ATCC 19615	Enterococcus faecalis ATCC 29212
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherlchia coli ATCC 8739	Klesiella pneumonlae ATCC 4352	Pseudomonas aeruginosa ATCC 9027
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Instructions for Use
1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates. Initially it may be necessary to change the dressing every 24 hours. When the exudates reduce, the frequency may be slowdown.

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Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.
5. LUOFUCON® Silver Foam Dressing is intended for short-term use up to 28 days.

Adverse Reactions

LUOFUCON® Silver Foam Dressing has been subjected to independent standard for *in vitro* biocompatibility tests, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of the studies indicated that LUOFUCON® Silver Foam Dressing is safe for its intended use.

Specifications (All models are presented with both 3mm and 5mm thickness)

Foam or Foam With PU Backing (mm x mm)	PU or Non-woven Adhesive Backing (mm x mm)
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
120×100	150×150(100×100)
120×120	180×180(110×110)
150×100	
150×150	
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in sealed, cool and dry place and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture

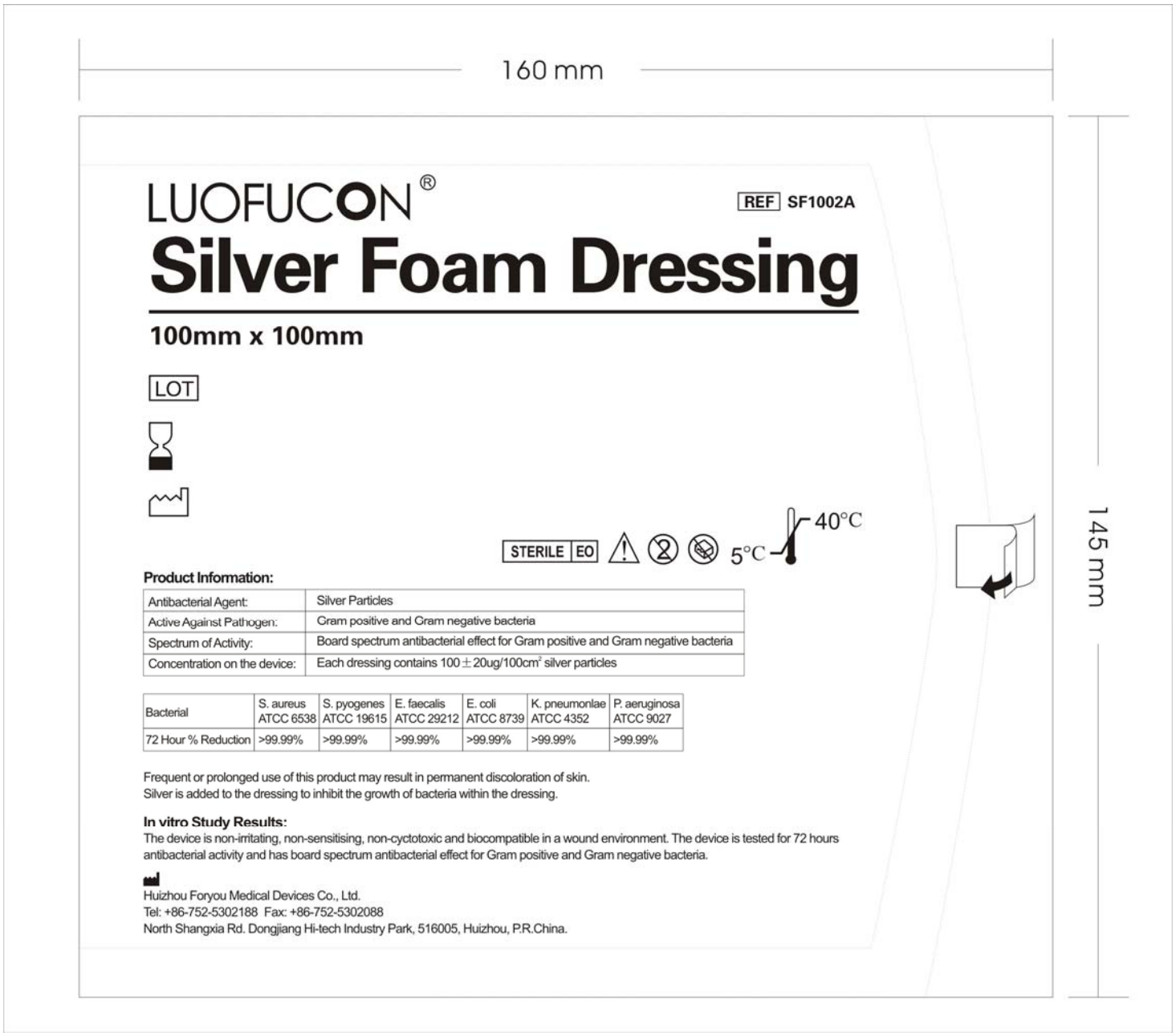
Manufacturer: Huizhou Foryou Medical Devices Co.,Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger



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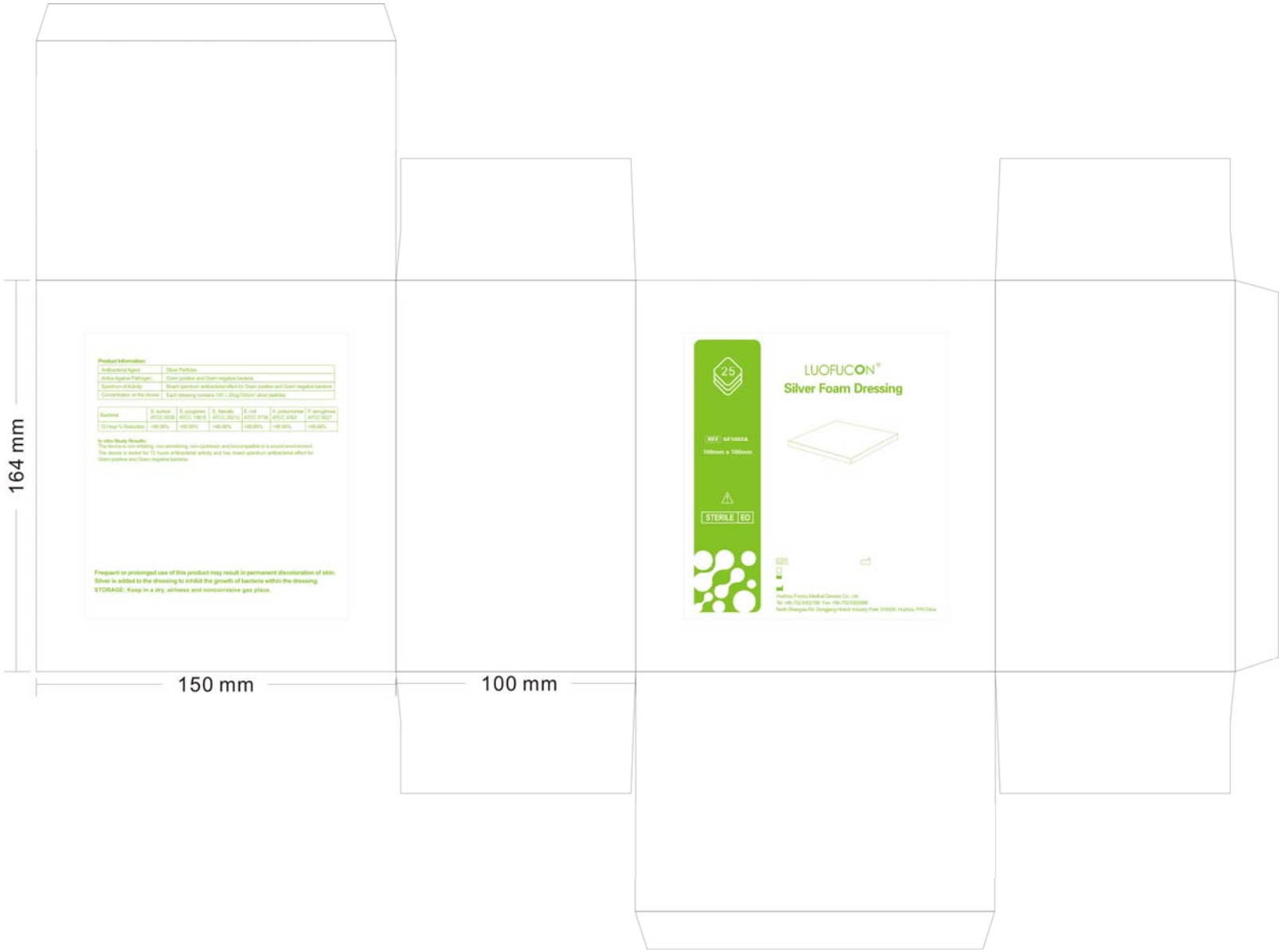
13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 13: Labeling: Prescription



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Section 14: Sterility and Shelf Life

Luofucon Silver Foam Dressing is sold directly to users after EtO sterilization validation to ISO 11135-1:2007, the sterilization method to be used is ethylene oxide with overkill approach. The details are the following:

14.1 Sterility Validation

The ethylene oxide method used to sterilize our "Luofucon Silver Foam Dressing" was validated following ISO 11135-1:2007. The method validation report can be found in **Appendix 1.**

Foam dressing without silver deposition was used to validate the procedure. Because of the general antibacterial activity of the silver ion, foam dressing without silver deposition has higher level of micro-organisms, thus represents the worst case scenario.

14.1.1 Reference of Standard: ISO-11135-1:2007

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: Yes. Foam dressing prior to silver deposition was used to validate the procedure. Justification: Foam dressing without silver is more difficult to sterilize (because silver itself is an antibacterial agent) thus represent the worst case scenario.

The name and address of test laboratory: In house

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Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	Yes
3	Terms and definitions	Yes
4	Quality management systems	Yes
5	Sterilizing agent characterization	Yes
6	Process and equipment characterization	Yes
7	Product definition	Yes
8	Process definition	Yes
9	Validation	Yes
10	Routine monitoring and control	Yes
11	Product release from sterilization	Yes
12	Maintaining process effectiveness	Yes

14.1.2. Validation Method

Sterilization method was validated following ISO-11135-1:2007. Ethylene oxide is used as the sterilization method. The method validation report is in Appendix 1.

Overkill approach (Half-cycle approach) is used following Annex B of the standard. A total of three consecutive experiments resulting in total inactivation of the biological indicators were performed in order to confirm the minimum exposure time. The specified exposure time doubles this minimum time. A cycle of short duration was also run to demonstrate the adequacy of the recovery technique.

Validation includes installation qualification, operational qualification, and process qualification.

Installation qualification (IQ) demonstrated that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

Operational qualification (OQ) demonstrated that the installed equipment is capable of delivering the specified process within defined tolerances.

The microbiological PQ was performed in the production chamber using defined process parameters selected to deliver less lethality than the specified sterilization process. The results demonstrated that, on application of the sterilization process, the specified requirements for sterility are met.

Physical PQ included a minimum of three planned qualification runs in which all the specified acceptance criteria are met. The results demonstrated reproducibility of the process and the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specifications.

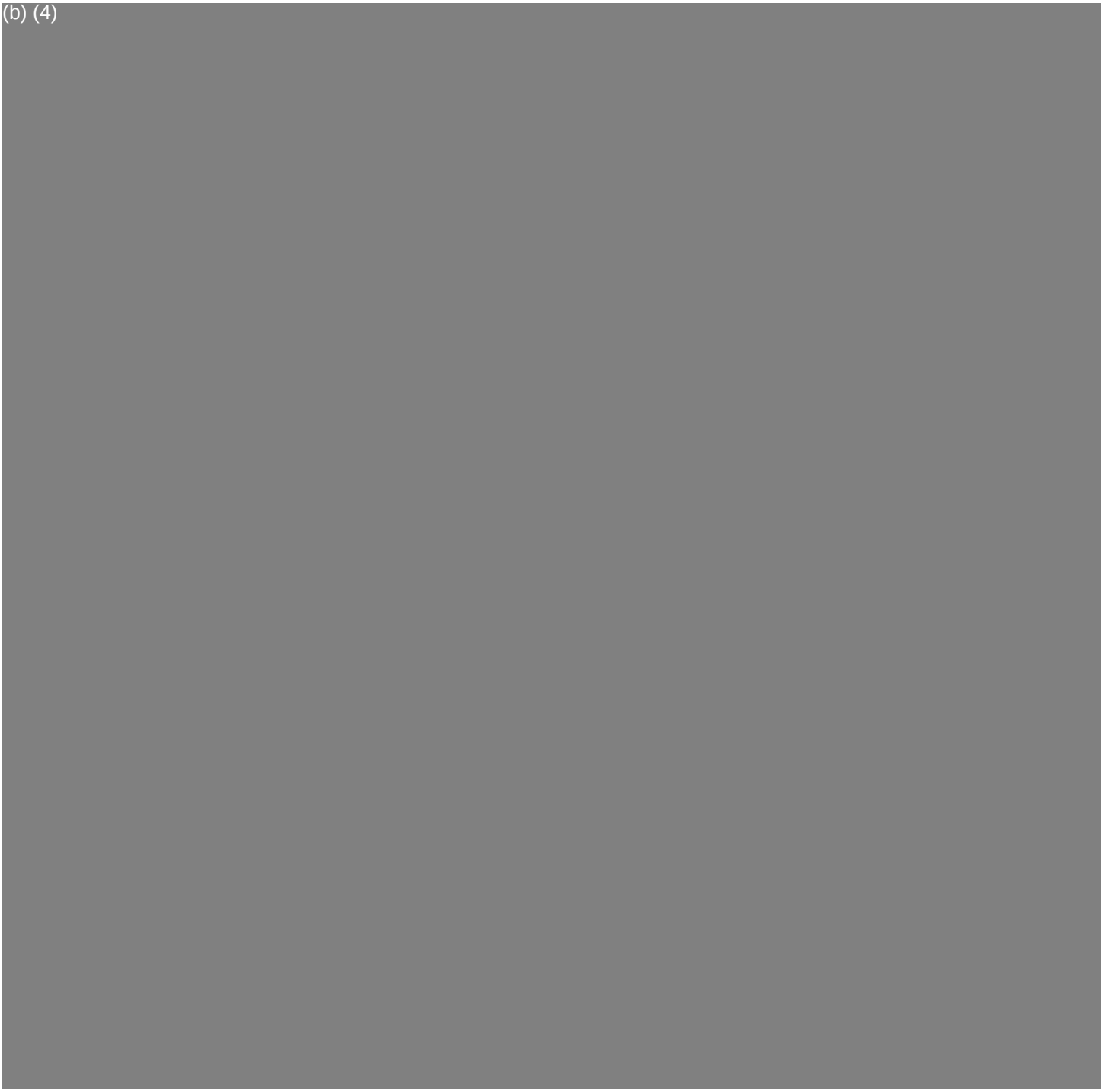
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Section 14: Sterility and Shelf

The validated sterilization parameters are the following:

(b) (4)



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(b) (4)

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14.1.4. SAL Level

The SAL level was found to be NMT 10^{-6} during our experiments.

14.2 Product Packaging

Luofucon Silver Foam Dressing is packaged in single use flexible package. Packages are supplied as preformed sterile barrier systems where all the seals have been formed except at the bottom. This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. A sealant layer is applied to allow heat-sealing of the two layers together.

The material, sterile barrier system, and product packaging are designed following the suggestions provided by ISO-11607-1. They have been proven to maintain sterility of terminally sterilized medical devices during storage, transportation, and distribution, until the point of use.

Table 14.3: Summary of packaging information involved in this submission

Immediate Packaging	Enforced paper- Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging	Paper Box
Outer Packaging	Corrugated Board Carton

14.3 Shelf Life Determination

The shelf life was determined by real time aging for products stored under ambient conditions. The proposed shelf life is two years.

14.3.1 Physical Properties

For real time aging test, products were stored under 25 ºC and 60% RH. Representative test results are summarized for Lot No.: S201107001; size100×100×3 mm; production date: July 12, 2011.

Both performance properties and packaging integrity were evaluated for up to two years.

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Physical properties were tested against product specifications as detailed in Section 11, except for silver content. Silver content is not expected to change over the course of time. All test results met specification and the results are summarized in the Table 14.4 below.

Table14.4: Representative Product Physical Properties for Two Year Real Time Aging Study

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×3±1mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.112	0.108	0.113
Absorbance	≥10g/g	12.6	12.3	11.2
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.47	4.44	4.56
Loss On Drying	≤6.0%	3.1%	4.1%	4.4%

14.3.2 Antibacterial Properties

Antibacterial properties were tested following standard AATCC-100:2004. Detailed test procedures are described in Section 18.7.2. In brief, an inoculum of the chosen challenge organism is absorbed into the test article and allowed to incubate for approximately 24 hours. The surviving challenge organisms are enumerated and compared to an untreated control.

Total of six bacteria (three Gram positive and three Gram negative) were tested:

Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 19615)
Enterococcus faecalis (ATCC 29212)
Escherichia coli (ATCC 8739)
Pseudomonas aeruginosa (ATCC 9027)
Klebsiella pneumoniae (ATCC 4352)

The antibacterial results after two years of ambient storage are presented in Table 14.5. The test was performed by Guangdong Detection Center of Microbiology, as an independent verification by third party.

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Table 14.5: Silver Foam Sample: Antibacterial activity results at Two Year Time Point. Size 100 x 100 x 3mm. The two year time point date was tested on Lot S201107001, manufacture date: July 12, 2011, test date: Sept 2013.

Bacterial	**Staphylococcus aureus ATCC 6538**			**Streptococcus pyogenes ATCC 19615**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	4.8×10^5/mL			4.7×10^5/mL		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28
Day-3 Inoculum Concentration	4.8×10^5			4.7×10^5		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28

Bacterial	**Enterococcus faecalis ATCC 29212**			**Escherlchia coli ATCC 8739**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.3×10^5/mL			5.2×10^5/mL		
Initial Contact time	2.1×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.0×10^6	2.0×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.32	>4.30	>4.32	>4.30	>4.30	>4.30
Day-3 Inoculum Concentration	5.3×10^5			5.2×10^5		
Initial Contact time	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.32	>4.3	>4.32	>4.30	>4.30	>4.30

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Bacterial	**Klesiella pneumonlae ATCC 4352**			**Pseudomonas aeruginosa ATCC 9027**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.0×10^5/mL			5.3×10^5/mL		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32
Day-3 Inoculum Concentration	5.0×10^5			5.3×10^5		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32

[a]: Inoculum Concentration is presented as CFU/ 1.0ml, while 4.0 mL was actually used each time to give 1.0-2.0 x 10^6 CFU.

The results show that the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

14.3.3 Packaging Integrity

Packaging integrity were tested for tensile strength (following suggestions by ASTM F88), dye penetration (following suggestions by ASTM F1929-98: 2004), and sterility. The results are summarized in Table 14.6. All pre-defined criteria were met for up to two years.

Table14.6: Representative Packaging Integrity Results for Two Year Real Time Aging Study

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.12	2.98	2.90
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

14.3.3 Conclusion for Aging Tests

Based on the above results, Luofucon Silver Foam Dressing is stable for up to two year under normal storage conditions. The product shelf life is designated as two years on the labeling.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 15: Biocompatibility

This section contains the following information

15.1 Cytotoxicity 2
15.1.1 Reference of Standard 2
15.1.2 Experimental 3
15.1.3 Results and Conclusion: 4
15.2 Sensitization Test 5
15.2.1 Reference of Standard 5
15.2.2 Experimental 6
15.2.3 Results and Conclusions: 8
15.3 Irritation Test 9
15.3.1 Reference of Standard 9
15.3.2 Experimental 10
15.3.3 Results and Discussions: 10
15.4 Systematic Toxicity 12
15.4.1 Reference of Standard 12
15.4.2 Experimental 13
15.4.3 Results and Discussions: 13

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Luofucon Silver Foam Dressing is used for the antibacterial and wound care purpose. Based on Table A.1 of ISO 10993-1, it is categorized as surface devices for bleached or compromised surface with prolonged duration. Cytotoxicity, sensitization, and irritation are needed for these devices. These tests are performed in accordance to ISO 10993-5 and ISO 10993-10. We also voluntarily added acute systematic toxicity test, which was performed per ISO 10993-11.

15.1 Cytotoxicity

Agar diffusion test described in ISO-10993-5:2009 was used to evaluate cytotoxicity of the material

In this test, test articles, positive and negative control samples were placed on top of agar in separate dishes. All dishes were incubated under appropriate conditions before the cells were stained with Neutral red. The decolorization zone and the cell lysis were examined using inverted microscope. The results demonstrated that there was no cytotoxicity for the test article, Luofucon Silver Foam Dressing.

15.1.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected:

(a) The standard allow the tester to select from performing test on extract of the sample, or performing test on the sample itself (section 4.1 of the standards). We choose to perform test on the sample itself

(b) For the same reason above, section 8.4 of the standard: Test by Indirect Contact (Agar Diffusion) was followed, as a proven and well accepted method for solid material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	Sample and Control Preparation	Yes.
5	Cell lines	Yes
6	Culture medium	Yes
7	Preparation of Cell Stock Culture	Yes
8	Test procedures	Yes. Followed procedures in 8.4.1
9	Test report	Yes
10	Assessment of results	Yes
11	Annex A-D	N/A

15.1.2 Experimental

Indirect test/Agar diffusion method was used in the determination of cytotoxicity.

More experimental details can be found in test report attached in **Appendix 1** of this submission.

Cell Preparation Procedure:
L-929 Mouse fibroblast cells were proliferated following normal procedures before they were trypsinized, collected, and adjusted to a concentration of 1.3 x 10^5/mL.

Growth Inhibition Test Procedure:
The liquid nutrient medium from each Peri dish was aspirated and replaced with freshly prepared 2.0 mL agar medium. After the agar medium solidified at room temperature, a 10.0 mm diameter disc portion of the test article was placed symmetrically on agar surface. Similarly, negative and positive control samples were also placed on top of agar. All Peri dishes were incubated at 37 °C in 5% CO_2 for 24 hours.

After incubation, the cells were stained with Neutral Red. The decolorization zone and the cell lysis were examined using inverted microscope.

Positive and Negative Control
High density polyethylene was used as the negative control, MEM medium with 0.5% phenol was used as positive control.

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Acceptance Criteria: Reactivity was graded based on Table 2 of ISO-10993-5 (also see table below). Score of negative control should be less than 1. Score of the positive control should be higher than 3. All readings from the test article should be no more than 2 to demonstrate none cytotoxicity.

Table 15.1 Reactivity Grade for Cytotoxicity Test

Grade	Description of the Zone
0	No detectable Zone around or under the sample
1	Some malformed or degenerate cells under the sample
2	Zone limited to area under the sample
3	Zone extends 0.5 to 1.0 cm beyond the sample
4	Zone greater than1 cm in extension from the sample

15.1.3 Results and Conclusion:

Three replicates were tested for each samples and controls. For all replicated tests, the reactivity grades for positive control, negative control, and sample are 4, 0, and 2, respectively. Based on ISO-10993-5, a numerical grade of greater than 2 (≥3) is considered cytotoxic. The test article, Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing has mild reactivity and in general is considered not toxic.

Table 15.2 Cytotoxicity Test Results

Group	Grade	Reactivity
Positive Control		
(1)	4	Severe
(2)	4	Severe
(3)	4	Severe
Negative Control		
(1)	0	None
(2)	0	None
(3)	0	None
Test Article		
(1)	2	Mild
(2)	2	Mild
(3)	2	Mild

The negative and positive control samples meet the requirement specified in acceptance criteria.

The test report (SDWH 2012-22572) can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.2 Sensitization Test

In selecting a new material for human contact in medical applications, it is important to ensure that the material does not stimulate the immune system to produce allergic response. This effect can be evaluated using procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". The maximization method was used.

15.2.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 7 of the standard: Delayed hypersensitivity tests. There are two most commonly used methods for delayed hypersensitivity. Maximization test was selected based on the nature and application of our materials. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes

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5	Pretest considerations	Yes
6	Irritation tests	Will be discussed in Section 15.3. of this submission
7	Sensitization tests	Yes. Note: There are two most commonly used methods for delayed hypersensitivity. The maximization was selected based on the nature and application of our material. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.
8	Key factors in the interpretation of test results	Yes

15.2.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

Number of Animals: Twenty test animals (ten for sesame oil and ten for 0.9% sodium chloride), five positive control animals, and ten negative control animals (five for sesame oil and five for 0.9% sodium chloride), each weighing 300-500 grams.

Extraction Condition:
The test article was extracted with sesame oil (as non-polar extract) and 0.9% sodium chloride (as polar extract), respectively, in the volume of $3cm^2$/mL. The extractions were performed at 37 °C for 72 hours.

Control Solutions:
Both sesame oil and 0.9% sodium chloride were used as negative control.
10 mg/mL 2,4 Dinitrofluorobenzene (DNFB) in acetone was used as positive control.

Intradermal Induction Phase
A pair of 0.1 ml intradermal injections were made of each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent (sesame oil or 0.9% sodium chloride).

Site B: The test sample (undiluted extract); negative control animals were injected with the chosen solvent alone (sesame oil for non-polar extract or 0.9% sodium chloride for polar extract); positive control animals were injected with the 10 mg/mL DNFB acetone solution alone.

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Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extract (50 %); the control animals were injected with an emulsion of 50:50 sesame oil or sodium chloride with Freund's complete adjuvant; positive control animals were injected with an emulsion of 50:50 10 mg/mL DNFB acetone solution and Freund's complete adjuvant.

Site A	Site A
Site B	Site B
Site C	Site C

Topical Induction Phase

At 6 days after completion of the intradermal induction phase, the test sample (using the concentration selected for site B) was topically administrated to the intrascapular region of each animal, using a filter paper (approximately 8 cm^2) soaked in the test sample extract, to cover the intradermal injection sites. The area was pretreated with 10 % sodium dodecyl sulfate massaged into the skin 24 h before the filter paper was applied. Filter paper was secured with elastic band. They were removed after 48 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Challenge phase

14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. Filter paper soaked in the test sample extract was administrated by topical application to upper flank of each animal (that areas were not treated during the induction stage). The patch was secured, and removed after 24 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Observation of animals

Challenge skin sites of the test and control animals were observed 24 h and 48 h after removal of the dressings. Observations were made with proper lighting.
Skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading for each challenge site and at each time interval.

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Readings were made without knowledge of the treatment. The test results were based on incidence and severity of the sensitization reaction.

Table 15.3: Grading Scale for Sensitization Test

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

15.2.3 Results and Conclusions:

Clinical Observations: None of the animals in the study showed abnormal clinical signs

Main Test Dermal Observations:
No irritations were observed on the test animals and negative control animals during the induction phase, for both sesame oil and 0.9% sodium chloride extracted samples.

The average grade for positive control animals is 2 from both reports SDWH 2013-21069 and SDWH 2013-21070.

None of the test animals challenged with the test article were observed with sensitization response at any time point of the challenge phase, indicating a 0% incidence. The severity was calculated as "0" at each time point, for both sesame oil and 0.9% sodium chloride extracted samples.

Conclusion:
Based on the above results, material used in the Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing does not elicit a sensitization response.

The following test reports can be found in **Appendix 1** of this submission.
SDWH 2013-21824 for Sesame Oil and negative control
SDWH 2013-21714 for Sodium Chloride and negative control
SDWH 2013-21069 for positive control
SDWH 2013-21070 for positive control

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.3 Irritation Test

The irritation test was conducted following procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". Human test was not conducted, as our products are made of solid material, thus don't have a high human exposure concentration, such as cosmetics.

15.3.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 6 of the standard: Irritation Tests. Section 6.4: Human skin irritation test is not performed. Human tests usually are performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes
5	Pretest considerations	Yes
6	Irritation tests	Yes. Note: Section 6.4: Human skin irritation test is not performed. Human tests usually are

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

		performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.
7	Sensitization tests	Discussed in Section 15.2 of this submission
8	Key factors in the interpretation of test results	Yes

15.3.2 Experimental

Test articles and controls were cut into pieces in the size of 2.5 cm x 2.5 cm.

Only animals with healthy skin were used. 4 sites were designated on each rabbit, with 2 sites on each side of the back, for test and control purpose, respectively. Total three animals were used.

Test material and control were applied directly to the shaved skin of three adult New Zealand White rabbits. After minimum four hours exposure, the patches were removed. Observations for skin irritations were conducted after 1, 24, 48, and 72 hours. The scores were totaled and averaged for the test article and negative control. The primary irritation index was then calculated.

Table 15.4: Grading Scores System Used in Irritation Test

Response category	Comparative Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2-4.9
Severe	5-8

15.3.3 Results and Discussions:

The results are summarized in the table below.

Table 15.5: Summary of Irritation Test Results

Sample	Test Article	Negative Control	Positive Control
1 hour	0.0	0.0	2
24 hours	0.0	0.0	3
48 hours	0.0	0.0	3
72 hours	0.0	0.0	2

The mean scores for both the test article and negative control are 0 for 1, 24, 48, and 72 hours. Test article does not induce irritation to skin.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The mean scores for positive control are 2, 3, 3, 2 for 1, 24, 48, and 72 hours.

The test report SDWH 2013-21715 for test article and negative control, and test report SDWH 2013-20111 for positive control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

15.4 Systematic Toxicity

The acute systematic toxicity test was conducted following procedures described in ISO 10993-11:2006 Standard, "Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity". The acute systematic toxicity was evaluated by the intraperitoneal injection of the extraction solution at 50 mL/kg. The symptom of toxicity and weight growth of test mice were observed and recorded daily. The results demonstrated the lack of systematic toxicity of the test article.

15.4.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

In Section 6 of the standard: Acute systematic toxicity by intraperitoneal application described in section 6.5.5. was followed

Any requirements that were not applicable to the device: Section 6.6 (Subacute systematic toxicity), Section 6.7 (Subchronic systematic toxicity), Section 6.8 (Chronic toxicity and carcinogenicity), and Section 7 (Pyrogenicity).

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Definitions	N/A
4	Test Sample Requirements and Recommendations	Yes
5	Method for Extraction from Medical devices	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6	Selection of Test Procedures for Systematic Toxicity	Yes. Note: Acute Systematic Toxicity described Section 6.5.5 was followed.
7	Selection of Test Procedures for Pyrogenicity	Not performed
8	Assessment of Results	Yes
9	Test report	Yes

15.4.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

The test article was extracted with sesame oil or saline (0.9% sodium chloride) in the volume of 30 cm^2/10 mL. The extraction was at 37 °C for 72 hours. The sample was completely dissolved as clear solution.

Sesame oil or saline was used as control solution.

Twenty mice were randomly divided into four groups: five mice for sesame oil test group, five mice for saline test group, five mice for sesame oil control group, and five mice for saline control group. Sample extract or control solution (saline) was administered by intraperitoneal injection at a dose of 50 mL/kg. The instant response of each mouse was observed after injection. Furthermore, monitor and record the status of the test and control animals daily for three days.

15.4.3 Results and Discussions:

Acceptance Criteria:
Within the 72 hours of observation period, the toxicosis response of the test group is no greater than the control group.

Results and Discussions
Within the monitoring period of 4, 24, 46, and 72 hours, the toxicosis response of the test group was no greater than the control group for both Saline and Sesame Oil groups. In addition, weight continued to increase for both the test and control group animals.

Conclusions
The test material showed no sign of acute systematic toxicity.

The test reports (SDWH 2013-21825, SDWH 2013-21716) for test article and negative control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 16: Software

Our device does not contain software. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 17: Electromagnetic Compatibility and Electrical Safety

Our device does not contain electrical components. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 18: Performance Testing – Bench

This section contains the bench performance testing results for the Luofucon Silver Foam Dressing described in this submission. The tests including the following:

Section 18.1 Density 2
Section 18.1.1 Experimental: 2
Section 18.1.2 Results and Discussions: 2
Section 18.2 Absorbency Test: Free Swell Absorption Capacity 3
Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002 3
Section 18.2.2 Experimental: 4
Section 18.2.3 Results and Discussions: 4
Section 18.3: Loss on Drying 5
Section 18.3.1: Reference to Standard USP 34 General Chapter <731> 5
Section 18.3.2: Experimental 5
Section 18.3.3: Results and Discussions 6
Section 18.4: pH Value 7
Section 18.4.1: Reference to Standard USP<791> 7
Section 18.4.2: Experimental 7
Section 18.4.3: Results and Discussions: 8
Section 18.5: Silver Content 9
Section 18.5.1: Reference to General Test Procedure EPA 6010C-2007 9
Section 18.5.2: Experimental 10
Section 18.5.3: Results and Discussions: 11
Section 18.6: Antibacterial Activity 12
Section 18.6.1: Reference to the AATCC 100-2004 12
Section 18.6.2: Experimental 13
Section 18.6.3: Testing Results 16
Section 18.6.4: Discussion of Testing Results 19
Section 18.7: Determination of Minimum Effective Concentration 21
Section 18.7.1: Experimental 21
Section 18.7.2: Results 21
Section 18.7.3: Discussions and Conclusion 24
Section 18.8: Silver Leachablity Study 25
Section 18.8.1: Experimental 25
Section 18.8.2: Results and Discussions: 26

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.1 Density

Density is an important parameter used in product quality control.

Section 18.1.1 Experimental:

The weight of the material was determined by calibrated balance. The width, thickness, and length of the sample were measured by calibrated ruler. Density was calculated as gram/cm^3

Acceptance Criteria: 0.09-0.18 g/cm^3

Section 18.1.2 Results and Discussions:

Shown below in Table 18.1 are exemplary density results from Lot S201305001 (100×100×3mm)

Table18.1: Exemplary Density Test Results for Lot S201305001

Sample #	Density g/cm^3
1	0.120
2	0.104
3	0.105
Average	0.110
% RSD	8.2%

In this exemplary measurement, average density is 0.110 g/m^3, and %RSD is 8.2 for three samples. The results met the product specification of 0.09 – 0.18 g/cm^3.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 18.2 Absorbency Test: Free Swell Absorption Capacity

Absorptive capacity is an important feature to assess the performance of dressings, especially these used on moderately to heavily exuding wounds.

The test was performed following BS EN 13726-1:2002: Test Methods for Primary Wound Dressings-Part 1: Aspects of absorbency. Section 3.2 of the standard: Test for Absorbency: Free Swell Absorption Capacity was chosen.

This chosen procedure is appropriate for dressings which stays physically intact and reaches maximum absorptive capacity within 30 min under the test conditions. This procedure is suitable for most types of foam dressings

Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any options the standard provides: Only Section 3.2: Test for Absorbency: Free Swell Absorption Capacity was chosen. The other test procedures (Sections 3.3 to 3.7) do not apply based on the nature of our product.

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Tested In-house

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Terms and Definitions	Yes
3	Test Methods for Absorbency	Yes
3.1	Test Conditions	Yes
3.2	Free Swell Absorption Capacity	Yes
3.3	Fluid Handling Capacity	Not Apply
3.4	Fluid Affinity of Amorphous Hydrogel Dressings	Not Apply
3.5	Gelling Characteristics	Not Apply
3.7	Dispersion Characteristics	Not Apply

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.8	Dispersion/Solubility of Hydrogel Dressings	Not Apply

Section 18.2.2 Experimental:

The tests were carried out at at (21 ± 2) °C and relative humidity of 60 % RH ± 15 % RH.

Test solution was prepared by dissolving appropriate amount of sodium chloride and calcium chloride dihydrate in deionised water to make a solution contains 142 mmol of sodium ions and 2,5 mmol of calcium ions as the chloride salts. This solution has an ionic composition comparable to human serum or wound exudate.

A single sample was cut to 5cm x 5cm, weighed and placed in a Petri dish.

Test solution corresponding to 40 times the mass of sample was pre-warmed to (37±1) °C and added to the sample. The sample was then transferred to the oven and allowed to stand for 30 min at (37±1) °C.

The sample was suspended by forceps on one corner or by one end as appropriate, for 30 s before it was weighed.

The absorptive capacity was calculated as the average mass of solution retained per gram of sample.

Acceptance Criteria: ≥10.0g/g

Section 18.2.3 Results and Discussions:

Shown below in Table 18.1 are exemplary results for three samples tested from Lot S201305001 (100 x 100 x 3 mm dressing)

Table18.2: Free Swell Absorption Test Results for Lot S201305001

Sample #	g/g
1	14.91
2	13.67
3	12.92
Average	13.8
% RSD	7.3%

Average absorbency is 13.8 g/g, and %RSD is 7.3 for three samples. The results met the product specification of free swell absorption ≥10.0g/g.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.3: Loss on Drying

Loss on Drying was tested following USP 34 General Chapter <731>: Loss on Drying

Section 18.3.1: Reference to Standard USP 34 General Chapter <731>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The Standard does not have sections	Loss on Drying	Yes

Section 18.3.2: Experimental

The dressing was cut into 5mm x 5mm. About 1 gram was weighed. An appropriate glass-stoppered, shallow weighing bottle was dried for about 30 minutes under the same conditions to be employed in the determination and cooled to room temperature in a desiccator. The test specimen was placed in the bottle, replaced the cover, and the weight of the bottle and the contents were recorded accordingly. The loaded bottle was then placed in the drying chamber, the stopper was removed and was also left in the chamber. The drying lasted for three hours at 105 °C. Upon opening the chamber, bottle was closed promptly, and was allowed to cool to room temperature in a desiccator before weighing.

Acceptance Criteria: ≤6%

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.3.3: Results and Discussions

Shown below in Table 18.4 are exemplary results for three samples tested from Lot S201305001 (100 x 100 x 3 mm dressing)

Table18.4: Loss on Drying Test Results: Lot S201305001

Sample #	% Loss	Average	%RSD
1	4.97%	4.98%	12.4%
2	4.37%		
3	5.61%		

The average loss on drying was 4.98% with %RSD of 12.4, met the product specification of ≤6%

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 18.4: pH Value

The dressing sample is leached in water and the pH value of the solution was tested following USP 34 General Chapter <791>: pH

Section 18.4.1: Reference to Standard USP<791>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The monograph does not contain any sections	pH	Yes

Section 18.4.2: Experimental

The dressing was cut into small pieces. About one gram was weighed to the nearest 0.01g, and 25mL of distilled water without carbon dioxide was added. The solution was then stirred at (37±1)℃ for 24h to get leaching solution. The pH was calibrated and pH value of the leaching solution was determined following USP 34 General Chapter <791>

Acceptance Criteria: pH value should be between 4.0 – 9.0.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.4.3: Results and Discussions:

Shown below in Table 18.4 are exemplary results for three samples tested from Lot S201305001 (100 x 100 x 3 mm dressing).

Table18.4: Exemplary pH Test Results: Lot S201305001

Sample #	pH	Average	%RSD
1	4.72	4.73	0.6
2	4.70		
3	4.76		

The average pH value for this exemplary lot was 4.73 with %RSD of 0.6, met the product specification of 4.0 – 9.0.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 19: Performance Testing: Animal

No animal testing was performed for this device.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 20: Performance Testing – Clinical

No clinical testing is not necessary for our device. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Attachment 1 Form FDA 3654: Standards Data Report for 510(k)

The following FDA recognized Standards are referenced in this submission, and their respective Form 3654's are included in this Attachment 1:

- Standard Data Report for ISO 10993:5
- Standard Data Report for ISO 10993:10
- Standard Data Report for ISO 10993:11
- Standard Data Report for ISO 11135:1
- Standard Data Report for EN13726
- Standard Data Report for USP 34 <731>
- Standard Data Report for USP 34 <791>
- Standard Data Report for AATCC-100

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-5:2009: Biological Evaluation of medical Devices", Part 5 – Tests for In Vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO-10993-5:2009: Biological Evaluation of medical Devices", Part 5 – Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Sample and control preparation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
The standard (Section 4.1) allows the options of performing test on extract of the sample, or performing test on the sample itself

DESCRIPTION
We choose to perform test on the sample itself

JUSTIFICATION
Perform test on the sample itself allows direct evaluation of the cytotoxicity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test procedures	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Standard provide three options: extraction, direct contact, and indirect contact

DESCRIPTION
Section 8.4. of the standard:Test by Indirect Contact (Agar Diffusion) was followed

JUSTIFICATION
Test by Indirect Contact (Agar Diffusion) is a well accepted method for solid material.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-10:2010: Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO-10993-10:2010: Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Section 6.4: Human skin irritation test was not performed

DESCRIPTION

Section 6.4: Human skin irritation test was not performed

JUSTIFICATION

Human tests are needed for chemicals that human exposure is high (cosmetics). Our product is not in this category.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Standard provide two options for hypersensitivity. Maximization method was used in our test.

DESCRIPTION

Maximization method was used in our test.

JUSTIFICATION

Maximization method is more suited for single chemical. Buehler method is more suited for composite chemicals.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-11:2006: Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO-10993-11:2006: Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of Test Procedures for Systematic Toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
The standard (Section 6) allows the options of systematic toxcity tests based on mode and duration of patient contact

DESCRIPTION
We choose to perform acute systematic toxicity (Section 6.5).

JUSTIFICATION
Our product has modest patient contact duration.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Selection of Test Procedures for Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
This test is not performed

DESCRIPTION
Pyrogenicity test is not performed

JUSTIFICATION
Our product is not expected to have material related pyrogens

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1:2007: Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and r

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-331	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☒

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STANDARD TITLE
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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 13726-1:2002: Test methods for primary wound dressings — Part 1: Aspects of absorbency

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 13726-1:2002: Test methods for primary wound dressings — Part 1: Aspects of absorbency

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Test methods for absorbency	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Exclusion from Standard

DESCRIPTION

Only Free Swell Absorptive Capacity Test (Sec 3.2) was performed. Sections 3.3-3.7 were not performed.

JUSTIFICATION

Only Free Swell Absorptive Capacity is relevant to our product and in our product specifications.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

USP 34 General Chapter <731>; Loss on Drying

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Food and Drug Administration
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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP 34 General Chapter <791>: pH

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AATCC Test Method 100-2004 Antibacterial Finishes on Textile Materials: Assessment of

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AATCC Test Method 100-2004 Antibacterial Finishes on Textile Materials: Assessment of

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Evaluation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Selection of an option

DESCRIPTION
Section 11.2 of the standard allows calculation of %reduction by three different methods. We choose to use method 1.

JUSTIFICATION
B is lager than C, therefore, method 1 should be used

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Test Organisms	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Deviation to adapt the standard to the device

DESCRIPTION
The Standard mentioned two bacteria. We tested three Gram positive bacteria and three Gram negative bacteria.

JUSTIFICATION
Testing more bacteria allows better evaluation of the antibacterial property of our device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Quantitative Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Deviation to adapt the standard to the device

DESCRIPTION
The Standard suggested using (1-2) e5 inoculum per sample. We used (1-2) e6 inoculum per sample

JUSTIFICATION
Inoculation at (1-2) e6 allows us to evaluate Log 4 bacterial reduction.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Huizhou Foryou Medical Devices Co., Ltd.

2. Date of the Application/Submission Which This Certification Accompanies
06/06/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Huizhou

State/Province/Region
Guangdong

Country
China

ZIP or Postal Code
516005

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (086) 0752-5302188

(Fax): (086) 0752-5302020

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: Silver Foam Dressing

Classification Name: Dressing, wound, Drug

Trade Name: Luofucon Silver Foam Dressing

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Charles Shen	Official Correspondent

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	853 Dorchester LN, Unit-B
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	New Milford
State/Province/Region	NJ
Country	USA
ZIP or Postal Code	07646

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 001-608-217-9358

(Fax): 001-425-930-2155

14. Date of Certification

05/30/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Charles Shen

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

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Appendix 1: Test Reports

The Following test report is included in this Appendix

Biocompatibility:
Cytotoxicity: Report #: SDWH-2012-22572
Skin Irritation: Report #: SDWH-2013-21715
Skin Sensitization (Sesame Oil): Report #: SDWH-2013-21824
Skin Sensitization (NaCl): Report #: SDWH-2013-21715
System Toxicity (Sesame Oil): Report #: SDWH-2013-21825
System Toxicity (NaCl): Report #: SDWH-2013-21716

Sterilization Validation Report: #: JS-75-653

Antibacterial Test Report

Lufucon Silver Foam Dressing: Report #: 2013FM3413Ea
Lufucon Foam Control Dressing (without Silver): Report #: 2013FM3826E
Neutralization Test: Report #: 2013FM4107E

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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K141619/S1

FDA CDRH DMC

JUL 23 2014

Received

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: Revision for 510(k) Number: K141619, Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are also summarized below:

1. Administrative (9): There has been no prior submission. Identification statement has been added to Section 3 (Cover Letter)

2. Device Description (11): Chemical composition and function of the non-woven material layer in the fourth variant of your device has been added to page 3 of Section 11

3. Device Description (12): Description about the thicknesses of the secondary layers in the second, third, and fourth variants of your device have been added to pages 2-3, and page 9 (Table 11.5) of Section 11.

4. Product Labeling (17): Zoomed in product labeling has been added in Section 13 for legible reading.

5. Biocompatibility (29): Complete materials of construction for each of the variants of your device, including secondary layers and any adhesives have been added to page 2 of Section 15.

6. Other: Section 5 and Section 10 are also updated to be consistent with changes in Section 11.

43

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles shen

Charles Shen, Official Correspondent
Date: July 20, 2014

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: Revision for 510(k) Number: K141619, Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are also summarized below:

1. Administrative (9): There has been no prior submission. Identification statement has been added to Section 3 (Cover Letter)

2. Device Description (11): Chemical composition and function of the non-woven material layer in the fourth variant of your device has been added to page 3 of Section 11

3. Device Description (12): Description about the thicknesses of the secondary layers in the second, third, and fourth variants of your device have been added to pages 2-3, and page 9 (Table 11.5) of Section 11.

4. Product Labeling (17): Zoomed in product labeling has been added in Section 13 for legible reading.

5. Biocompatibility (29): Complete materials of construction for each of the variants of your device, including secondary layers and any adhesives have been added to page 2 of Section 15.

6. Other: Section 5 and Section 10 are also updated to be consistent with changes in Section 11.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles Shen, Official Correspondent
Date: July 20, 2014

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

Two copies are included: One paper copy and one eCopy.
The eCopy is an exact duplicate of the paper copy.
There were no prior submissions with FDA for the subject device.

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 $\mu g/cm^3$ silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Executive Summary

This section composes the following:

- Section 10.1: Concise description of the device, including the indications for use and technology;
- Section 10.2: Device Comparison
- Section 10.3: Concise Summary for Performance Testing

Section 10.1: Concise Description of the Device (including the indications for use and technology)

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane foam and silver particles, which absorbs wound exudate and releases silver in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane foam material consists of metallic silver that provides effective protection of the dressing against microbial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days period, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The product in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Section 10.2 Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 10.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial	Three days	Three days [a]

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Duration		
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has both single layered and double layered structure. This small difference does not impact the safety and efficacy of the two devices.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 10.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 10.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for four days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Section 10.3 Concise Summary for Performance Testing

The following Biocompatibility testing results are included in **Section 15** of this submission.

Purpose	Testing Standard
Cytotoxicity	ISO10993-5
Skin Irritation and Sensitization	ISO 10993-10
Systematic Toxicity	ISO 10993-11

The results show all materials are not cytotoxic, do not cause skin irritation, and sensitization, and have no systematic toxicity.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

The following bench performance testing results are included in **Section 18** of this submission for a representative lot.

Test items	Specification	Test Results	Test Method
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform	Visual
Dimension	Deviation ≤ ±5%	Conform	Calibrated ruler
Density	0.09-0.18 g/cm^3	0.110gram/m^3	Internal Method
Free Swell Absorption	≥10.0 g/g	13.8 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	4.98%	USP 34 <731> Loss on drying
pH	4.0～9.0	4.73	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	2.85 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria	AATCC 100: 2004

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we tested three (3) gram positive bacteria and three (3) gram negative bacteria, for the evaluation of broad spectrum antibacterial effectiveness of the silver foam dressing. The dressings are effective (>99.99% reduction) toward all six bacteria for three days.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 9
11.4 Summary of Test Results 10
11.5 List of All Materials Used 11
11.6 Manufacturing Process 12
11.7 Silver Compound Used in the Products and Silver Particle Size 14
11.8 Bonding Between Silver Particles and Silver Leachability 15
11.9 Antimicrobial Activity Spectrum (Profile) 18
11.10 Minimum Effective Concentration 18
11.11 Likely Silver Antibacterial Mechanism 19

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

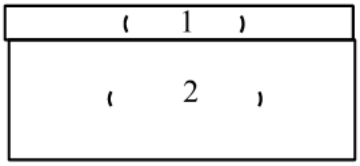
The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2, Table 11.5).

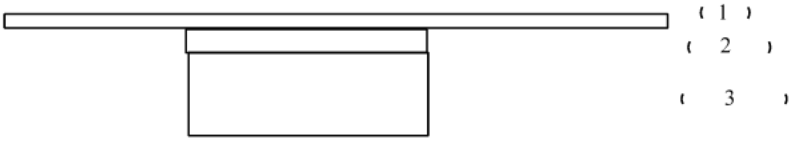
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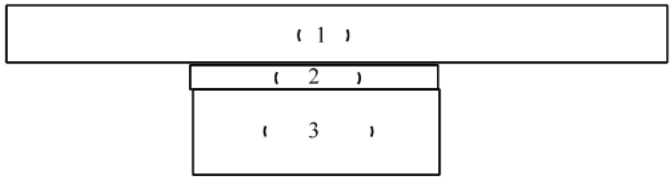
Illustrative drawing of the second variant: (1)) Thin polyurethane backing layer for cosmetic purpose (2) Thick polyurethane wound contacting layer

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.3, Table 11.5).



Illustrative drawing of the third variant: (1) Thin PET layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.4, Table 11.5).



Illustrative drawing of the fourth variant: (1) Non woven layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

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For the third and fourth variants, the adhesive is composed of 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

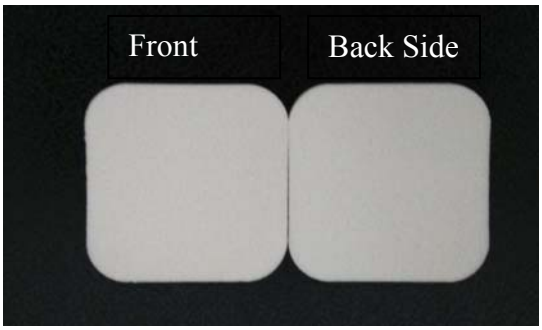
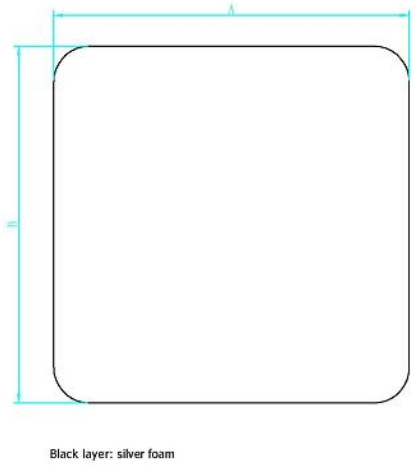
Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below. Secondary layer information are summarized in Table 11.5.

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Section 11: Device Description

Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

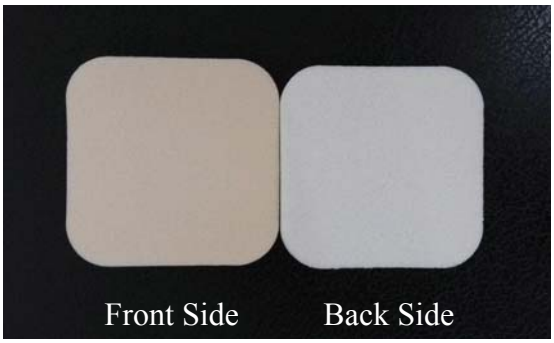
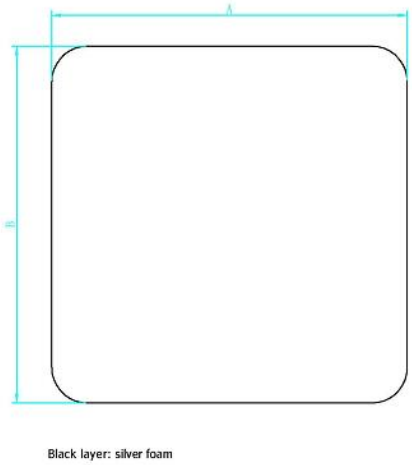
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

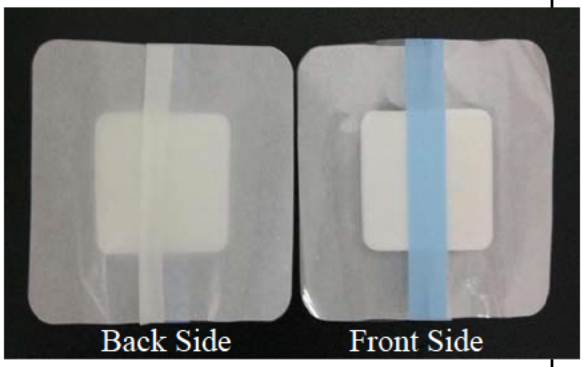
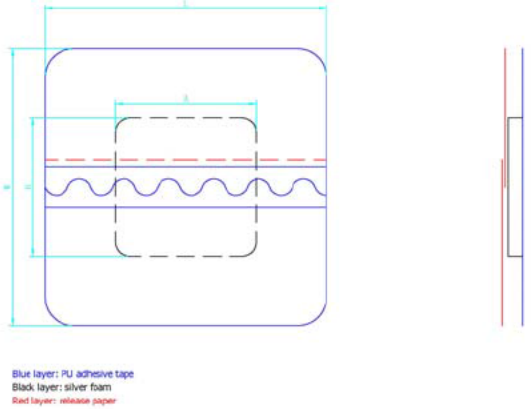
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

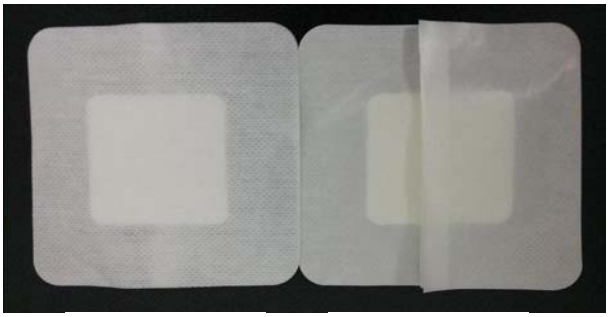
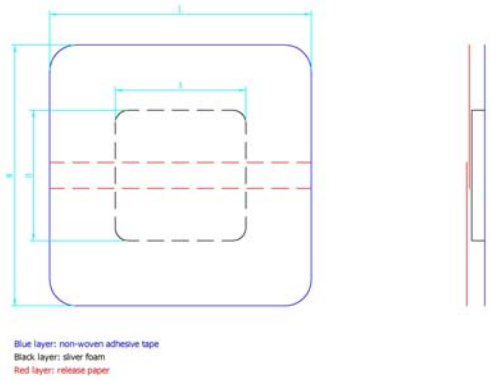
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.5: Secondary Layer Information Summary

Variant	Variant	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Packaging information is listed below:

Immediate Packaging:
Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging:
Paper Box
Outer Packaging:
Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.6. The biological specifications are shown in Table 11.7.

Table 11.6: Physical Specification of Luofucon Silver Foam Dressing

Test items	**Specification**	**Test Method [a]**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation $\leq \pm 5\%$	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying

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pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details are described in *Section 18: Performance Testing: Bench*

The biological specifications are shown in Table 11.7.

Table 11.7 Biological Specifications

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201305001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.8 and 11.9.

Table 11.8: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201305001, size 100 mm x 100 mm x 3 mm)

Test items	**Specification**	**Test Results**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5%	Conform
Density	0.09-0.18 g/cm^3	0.110 gram/m^3

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Free Swell Absorption	≥10.0 g/g	13.8 g/g
Loss on Drying	≤6%	4.98%
pH	4.0～9.0	4.73
Silver Content [a]	3±1 μg/cm^3	2.85 μg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

[a:] Incoming Quality Control

Table 11.9: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. One piece of silver dressing in the size of 100 x 100 x 3 mm were used and immersed in 20 mL of simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, 48, and 72 hours
Extraction temperature: 25 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry).

The test results are summarized in the Table 11.10 below. % of Total Silver is calculated using a nominal silver amount of 3 μg/cm^3 (total silver is 90 μg for 100 x 100 x 3 mm dressing)

The leachables are calculated as both daily leachable, which is the leached silver amount with 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

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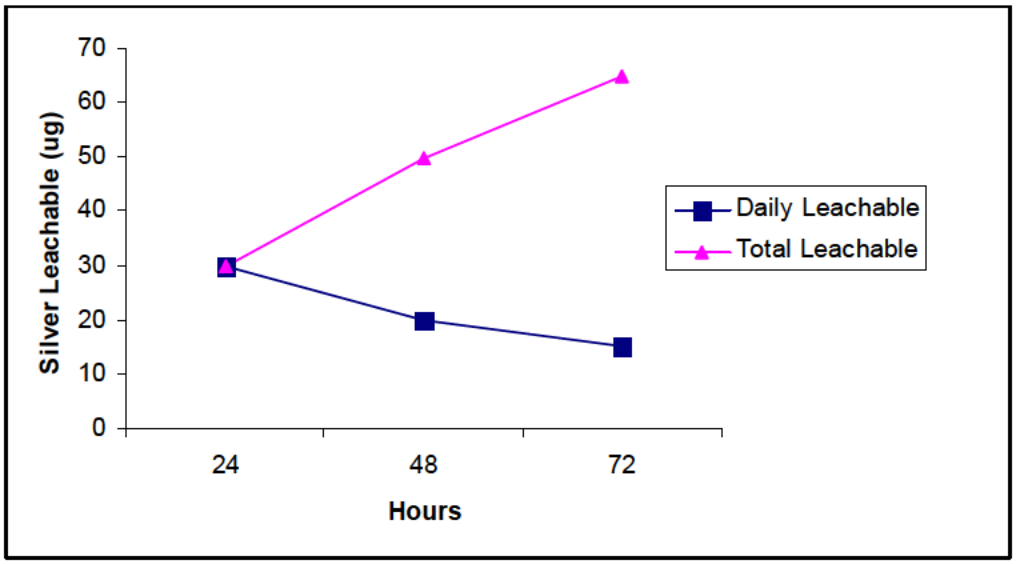
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Table 11.13: Silver Dressing Leachable Study. Test conditions are discussed above.

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Leachable (µg)	Daily leachable as % of Total Silver[a]	Total Leachable (µg)	Total Leachable as % of Total Silver[a]
24	1.50	20	30.0	33.3%	30.0	33.3%
48	0.99	20	19.8	22.0%	49.8	55.3%
72	0.75	20	15.0	16.7%	64.8	72.0%

[a]: 100 x 100 x 3 mm foam contains 90 µg silver, and was used in the calculation

Under this simulated condition, Luofucon Silver Foam Dressing leaches about 33.3% of the total silver during the first 24 hours, and leaches about 22.0%, and 16.7% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours about 72.0% of the total silver was leached out. This is also presented in the plot below:



This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

Since the nominal concentration of silver is 3±1 µg/ cm^3, after three days of recommended usage duration, at least 72.0% of silver is released, equivalent to at least 2.2 µg/cm^3. This number (2.2 µg/cm^3) will be shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, therefore causing much less skin discoloration effect.

Details of this experiment can be found in **Section 18**

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11.9 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.10 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.11 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 13: Proposed Labeling

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 6

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

RX Only
version: A/0

Product Name
LUOFUCON® Silver Foam Dressing

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment to accelerate healing process. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. LUOFUCON® Silver Foam Dressing can restrain the bacteria growing and reduce infection. LUOFUCON® Silver Foam Dressing has been tested *in vitro* and found to be effective against bacteria such as Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonsa aeruginosa and Klebsiella pneumoniae.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers (venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns (1st and 2nd degree)

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

Product Information:

Antibacterial Agent:	Silver particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 2-4ug/cm^3 silver

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity till day-3. The device has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Bacterial	Staphylococcus aureus ATCC 6538	Streptococcus pyogenes ATCC 19615	Enterococcus faecalis ATCC 29212
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherlchia coli ATCC 8739	Klesiella pneumonlae ATCC 4352	Pseudomonas aeruginosa ATCC 9027
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Instructions for Use
1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates. Initially it may be necessary to change the dressing every 24 hours. When the exudates reduce, the frequency may be slowdown.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.
5. LUOFUCON® Silver Foam Dressing is intended for short-term use up to 28 days.

Adverse Reactions

LUOFUCON® Silver Foam Dressing has been subjected to independent standard for *in vitro* biocompatibility tests, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of the studies indicated that LUOFUCON® Silver Foam Dressing is safe for its intended use.

Specifications (All models are presented with both 3mm and 5mm thickness)

Foam or With PU Backing (mm x mm)	PU or Non-woven Adhesive Backing (mm x mm)
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
120×100	150×150(100×100)
120×120	180×180(110×110)
150×100	
150×150	
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in sealed, cool and dry place and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture

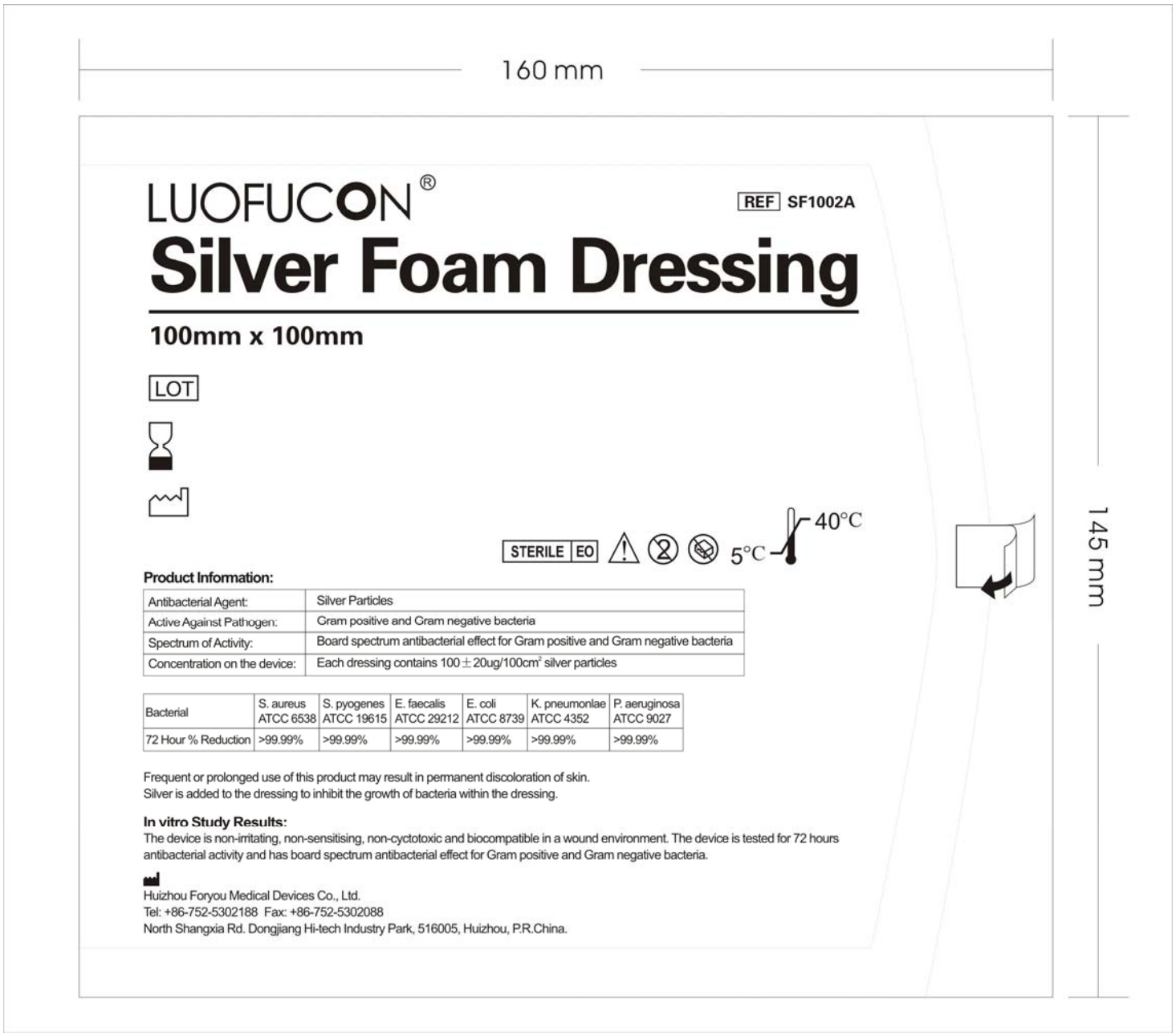
Manufacturer: Huizhou Foryou Medical Devices Co.,Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger



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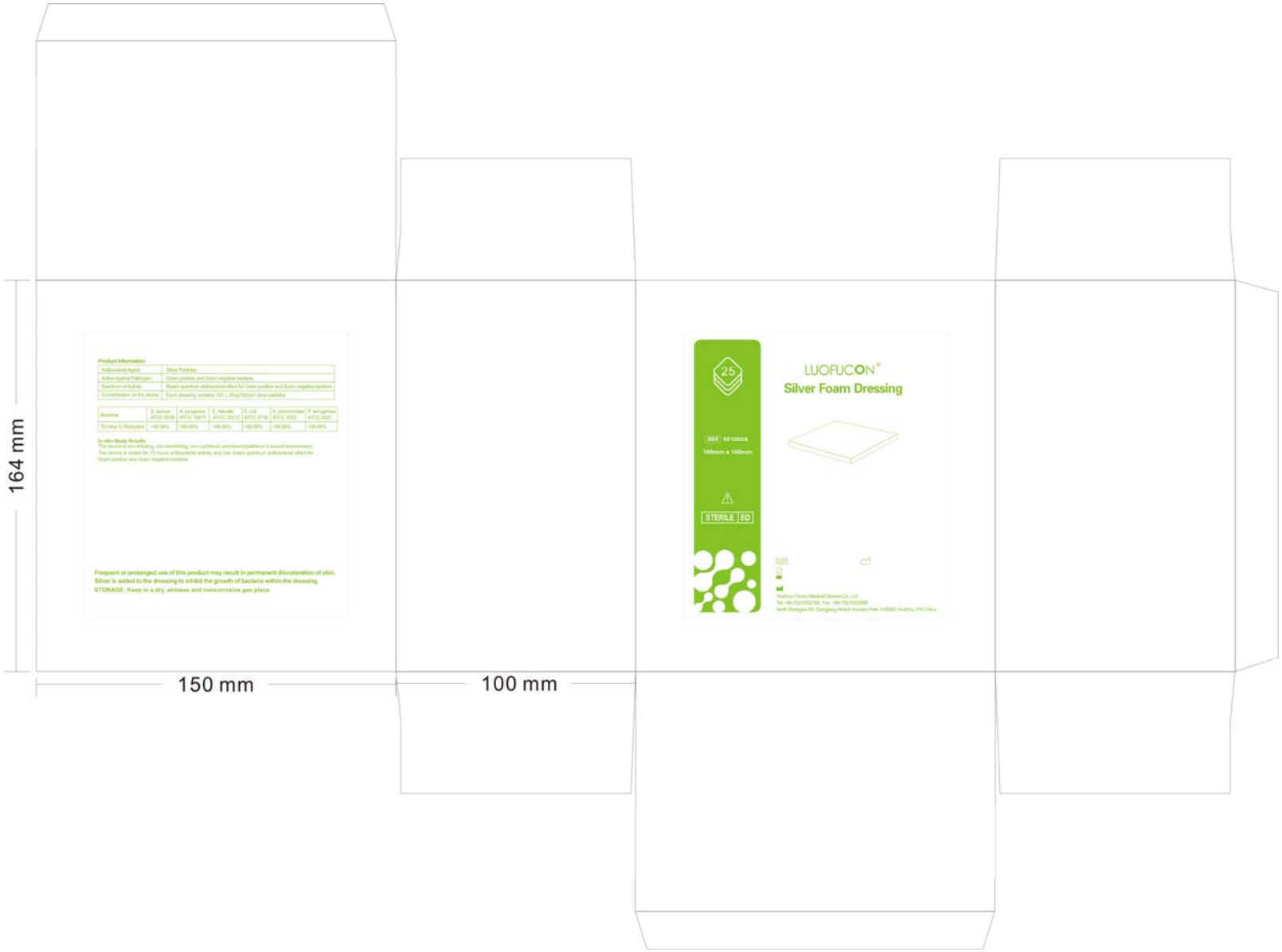
13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 13: Labeling: Prescription



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Zoom in on left side:

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogen:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 100±20ug/100cm^2 silver particles

Bacterial	S. aureus ATCC 6538	S. pyogenes ATCC 19615	E. faecalis ATCC 29212	E. coli ATCC 8739	K. pneumonlae ATCC 4352	P. aeruginosa ATCC 9027
72 Hour % Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

In vitro Study Results:
The device is non-irritating, non-sensitising, non-cyctotoxic and biocompatible in a wound environment.
The device is tested for 72 hours antibacterial activity and has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Frequent or prolonged use of this product may result in permanent discoloration of skin.
Silver is added to the dressing to inhibit the growth of bacteria within the dressing.
STORAGE: Keep in a dry, airiness and noncorrosive gas place.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zoom in on right side:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 15: Biocompatibility

This section contains the following information

15.1 Cytotoxicity 2
15.1.1 Reference of Standard 3
15.1.2 Experimental 4
15.1.3 Results and Conclusion: 5
15.2 Sensitization Test 6
15.2.1 Reference of Standard 6
15.2.2 Experimental 7
15.2.3 Results and Conclusions: 9
15.3 Irritation Test 10
15.3.1 Reference of Standard 10
15.3.2 Experimental 11
15.3.3 Results and Discussions: 11
15.4 Systematic Toxicity 13
15.4.1 Reference of Standard 13
15.4.2 Experimental 14
15.4.3 Results and Discussions: 14

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Luofucon Silver Foam Dressing is used for the antibacterial and wound care purpose. Based on Table A.1 of ISO 10993-1, it is categorized as surface devices for bleached or compromised surface with prolonged duration. Cytotoxicity, sensitization, and irritation are needed for these devices. These tests are performed in accordance to ISO 10993-5 and ISO 10993-10. We also voluntarily added acute systematic toxicity test, which was performed per ISO 10993-11.

Table below listed the chemical composition of each layer and their patient contact information.

Variant	Variant	Layers	Chemical Composition	Function
First Variant	Basic Model	Polyurethane Foam	Polyurethane	Wound Contact
Second Variant	Non-Adhesive Backing	Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact
Third variant	PU/PET Adhesive Backing	Adhesive	2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid in ethyl acetate/ alcohol	Skin contact /Non Wound contact
		Poly (ethylene terephthalate) Film	Poly (ethylene terephthalate)	Skin contact /Non Wound contact
		Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact
Fourth Variant	PU/Non-Woven Adhesive Backing	Adhesive	2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid in ethyl acetate/ alcohol	Skin contact /Non Wound contact
		Non Woven Film	viscose rayon & poly (ethylene terephthalate) fibers	Skin contact /Non Wound contact
		Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact

15.1 Cytotoxicity

Agar diffusion test described in ISO-10993-5:2009 was used to evaluate cytotoxicity of the material

In this test, test articles (polyurethane silver foam dressing, first variant), positive and negative control samples were placed on top of agar in separate dishes. All dishes were incubated under appropriate conditions before the cells were stained with Neutral red. The decolorization zone and the cell lysis were examined using inverted microscope. The

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results demonstrated that there was no cytotoxicity for the test article, Luofucon Silver Foam Dressing.

15.1.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected:

(a) The standard allow the tester to select from performing test on extract of the sample, or performing test on the sample itself (section 4.1 of the standards). We choose to perform test on the sample itself

(b) For the same reason above, section 8.4 of the standard: Test by Indirect Contact (Agar Diffusion) was followed, as a proven and well accepted method for solid material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	Sample and Control Preparation	Yes.
5	Cell lines	Yes
6	Culture medium	Yes
7	Preparation of Cell Stock Culture	Yes
8	Test procedures	Yes. Followed procedures in 8.4.1
9	Test report	Yes
10	Assessment of results	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11	Annex A-D	N/A

15.1.2 Experimental

Indirect test/Agar diffusion method was used in the determination of cytotoxicity.

More experimental details can be found in test report attached in **Appendix 1** of this submission.

Cell Preparation Procedure:
L-929 Mouse fibroblast cells were proliferated following normal procedures before they were trypsinized, collected, and adjusted to a concentration of 1.3×10^5/mL.

Growth Inhibition Test Procedure:
The liquid nutrient medium from each Peri dish was aspirated and replaced with freshly prepared 2.0 mL agar medium. After the agar medium solidified at room temperature, a 10.0 mm diameter disc portion of the test article was placed symmetrically on agar surface. Similarly, negative and positive control samples were also placed on top of agar. All Peri dishes were incubated at 37 °C in 5% CO_2 for 24 hours.

After incubation, the cells were stained with Neutral Red. The decolorization zone and the cell lysis were examined using inverted microscope.

Positive and Negative Control
High density polyethylene was used as the negative control, MEM medium with 0.5% phenol was used as positive control.

Acceptance Criteria: Reactivity was graded based on Table 2 of ISO-10993-5 (also see table below). Score of negative control should be less than 1. Score of the positive control should be higher than 3. All readings from the test article should be no more than 2 to demonstrate none cytotoxicity.

Table 15.1 Reactivity Grade for Cytotoxicity Test

Grade	Description of the Zone
0	No detectable Zone around or under the sample
1	Some malformed or degenerate cells under the sample
2	Zone limited to area under the sample
3	Zone extends 0.5 to 1.0 cm beyond the sample
4	Zone greater than1 cm in extension from the sample

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15.1.3 Results and Conclusion:

Three replicates were tested for each samples and controls. For all replicated tests, the reactivity grades for positive control, negative control, and sample are 4, 0, and 2, respectively. Based on ISO-10993-5, a numerical grade of greater than 2 (≥3) is considered cytotoxic. The test article, Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing has mild reactivity and in general is considered not toxic.

Table 15.2 Cytotoxicity Test Results

Group	Grade	Reactivity
Positive Control		
(1)	4	Severe
(2)	4	Severe
(3)	4	Severe
Negative Control		
(1)	0	None
(2)	0	None
(3)	0	None
Test Article		
(1)	2	Mild
(2)	2	Mild
(3)	2	Mild

The negative and positive control samples meet the requirement specified in acceptance criteria.

The test report (SDWH 2012-22572) can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.2 Sensitization Test

In selecting a new material for human contact in medical applications, it is important to ensure that the material does not stimulate the immune system to produce allergic response. This effect can be evaluated using procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". The maximization method was used.

15.2.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 7 of the standard: Delayed hypersensitivity tests. There are two most commonly used methods for delayed hypersensitivity. Maximization test was selected based on the nature and application of our materials. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes

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5	Pretest considerations	Yes
6	Irritation tests	Will be discussed in Section 15.3. of this submission
7	Sensitization tests	Yes. Note: There are two most commonly used methods for delayed hypersensitivity. The maximization was selected based on the nature and application of our material. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.
8	Key factors in the interpretation of test results	Yes

15.2.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.
Test article used was polyurethane silver foam dressing, first variant.

Number of Animals: Twenty test animals (ten for sesame oil and ten for 0.9% sodium chloride), five positive control animals, and ten negative control animals (five for sesame oil and five for 0.9% sodium chloride), each weighing 300-500 grams.

Extraction Condition:
The test article was extracted with sesame oil (as non-polar extract) and 0.9% sodium chloride (as polar extract), respectively, in the volume of $3cm^2$/mL. The extractions were performed at 37 °C for 72 hours.

Control Solutions:
Both sesame oil and 0.9% sodium chloride were used as negative control.
10 mg/mL 2,4 Dinitrofluorobenzene (DNFB) in acetone was used as positive control.

Intradermal Induction Phase
A pair of 0.1 ml intradermal injections were made of each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent (sesame oil or 0.9% sodium chloride).

Site B: The test sample (undiluted extract); negative control animals were injected with the chosen solvent alone (sesame oil for non-polar extract or 0.9% sodium chloride for polar extract); positive control animals were injected with the 10 mg/mL DNFB acetone solution alone.

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Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extract (50 %); the control animals were injected with an emulsion of 50:50 sesame oil or sodium chloride with Freund's complete adjuvant; positive control animals were injected with an emulsion of 50:50 10 mg/mL DNFB acetone solution and Freund's complete adjuvant.

Site A	Site A
Site B	Site B
Site C	Site C

Topical Induction Phase

At 6 days after completion of the intradermal induction phase, the test sample (using the concentration selected for site B) was topically administrated to the intrascapular region of each animal, using a filter paper (approximately 8 cm^2) soaked in the test sample extract, to cover the intradermal injection sites. The area was pretreated with 10 % sodium dodecyl sulfate massaged into the skin 24 h before the filter paper was applied. Filter paper was secured with elastic band. They were removed after 48 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Challenge phase

14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. Filter paper soaked in the test sample extract was administrated by topical application to upper flank of each animal (that areas were not treated during the induction stage). The patch was secured, and removed after 24 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Observation of animals

Challenge skin sites of the test and control animals were observed 24 h and 48 h after removal of the dressings. Observations were made with proper lighting.
Skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading for each challenge site and at each time interval.

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Readings were made without knowledge of the treatment. The test results were based on incidence and severity of the sensitization reaction.

Table 15.3: Grading Scale for Sensitization Test

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

15.2.3 Results and Conclusions:

Clinical Observations: None of the animals in the study showed abnormal clinical signs

Main Test Dermal Observations:
No irritations were observed on the test animals and negative control animals during the induction phase, for both sesame oil and 0.9% sodium chloride extracted samples.

The average grade for positive control animals is 2 from both reports SDWH 2013-21069 and SDWH 2013-21070.

None of the test animals challenged with the test article were observed with sensitization response at any time point of the challenge phase, indicating a 0% incidence. The severity was calculated as "0" at each time point, for both sesame oil and 0.9% sodium chloride extracted samples.

Conclusion:
Based on the above results, material used in the Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing does not elicit a sensitization response.

The following test reports can be found in **Appendix 1** of this submission.
SDWH 2013-21824 for Sesame Oil and negative control
SDWH 2013-21714 for Sodium Chloride and negative control
SDWH 2013-21069 for positive control
SDWH 2013-21070 for positive control

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.3 Irritation Test

The irritation test was conducted following procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". Human test was not conducted, as our products are made of solid material, thus don't have a high human exposure concentration, such as cosmetics.

15.3.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 6 of the standard: Irritation Tests. Section 6.4: Human skin irritation test is not performed. Human tests usually are performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes
5	Pretest considerations	Yes
6	Irritation tests	Yes. Note: Section 6.4: Human skin irritation test is not performed. Human tests usually are

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.
7	Sensitization tests	Discussed in Section 15.2 of this submission
8	Key factors in the interpretation of test results	Yes

15.3.2 Experimental

Test articles (polyurethane silver foam dressing, first variant) and controls were cut into pieces in the size of 2.5 cm x 2.5 cm.

Only animals with healthy skin were used. 4 sites were designated on each rabbit, with 2 sites on each side of the back, for test and control purpose, respectively. Total three animals were used.

Test material and control were applied directly to the shaved skin of three adult New Zealand White rabbits. After minimum four hours exposure, the patches were removed. Observations for skin irritations were conducted after 1, 24, 48, and 72 hours. The scores were totaled and averaged for the test article and negative control. The primary irritation index was then calculated.

Table 15.4: Grading Scores System Used in Irritation Test

Response category	Comparative Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2-4.9
Severe	5-8

15.3.3 Results and Discussions:

The results are summarized in the table below.

Table 15.5: Summary of Irritation Test Results

Sample	Test Article	Negative Control	Positive Control
1 hour	0.0	0.0	2
24 hours	0.0	0.0	3
48 hours	0.0	0.0	3
72 hours	0.0	0.0	2

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The mean scores for both the test article and negative control are 0 for 1, 24, 48, and 72 hours. Test article does not induce irritation to skin.
The mean scores for positive control are 2, 3, 3, 2 for 1, 24, 48, and 72 hours.

The test report SDWH 2013-21715 for test article and negative control, and test report SDWH 2013-20111 for positive control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.4 Systematic Toxicity

The acute systematic toxicity test was conducted following procedures described in ISO 10993-11:2006 Standard, "Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity". The acute systematic toxicity was evaluated by the intraperitoneal injection of the extraction solution at 50 mL/kg. The symptom of toxicity and weight growth of test mice were observed and recorded daily. The results demonstrated the lack of systematic toxicity of the test article.

15.4.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

In Section 6 of the standard: Acute systematic toxicity by intraperitoneal application described in section 6.5.5. was followed

Any requirements that were not applicable to the device: Section 6.6 (Subacute systematic toxicity), Section 6.7 (Subchronic systematic toxicity), Section 6.8 (Chronic toxicity and carcinogenicity), and Section 7 (Pyrogenicity).

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Definitions	N/A
4	Test Sample Requirements and Recommendations	Yes
5	Method for Extraction from Medical devices	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6	Selection of Test Procedures for Systematic Toxicity	Yes. Note: Acute Systematic Toxicity described Section 6.5.5 was followed.
7	Selection of Test Procedures for Pyrogenicity	Not performed
8	Assessment of Results	Yes
9	Test report	Yes

15.4.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

Test article used was polyurethane silver foam dressing, first variant.

The test article was extracted with sesame oil or saline (0.9% sodium chloride) in the volume of 30 cm^2/10 mL. The extraction was at 37 °C for 72 hours. The sample was completely dissolved as clear solution.

Sesame oil or saline was used as control solution.

Twenty mice were randomly divided into four groups: five mice for sesame oil test group, five mice for saline test group, five mice for sesame oil control group, and five mice for saline control group. Sample extract or control solution (saline) was administered by intraperitoneal injection at a dose of 50 mL/kg. The instant response of each mouse was observed after injection. Furthermore, monitor and record the status of the test and control animals daily for three days.

15.4.3 Results and Discussions:

Acceptance Criteria:
Within the 72 hours of observation period, the toxicosis response of the test group is no greater than the control group.

Results and Discussions
Within the monitoring period of 4, 24, 46, and 72 hours, the toxicosis response of the test group was no greater than the control group for both Saline and Sesame Oil groups. In addition, weight continued to increase for both the test and control group animals.

Conclusions
The test material showed no sign of acute systematic toxicity.

The test reports (SDWH 2013-21825, SDWH 2013-21716) for test article and negative control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA CDRH DMC
JAN 14 2015
Received

K141619/S2

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S002, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

"With regards to your intended use:

a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary. "

Response to FDA Comment 1:

1-CD

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The description, labeling, 510K Summary, and Indications for Use has been revised according to FDA suggestions.

FDA Comment 2:

You have provided a predicate device which also contains silver. In your submission, you state that your device has "relatively low silver release" "compared to other products in the market." However, you have not compared the differences, if any, in silver content between your device and your predicate device. If there is a difference in silver content, this may represent a meaningful difference in the technological characteristics of your device. Please discuss any differences in silver content and, if differences exist, please provide a justification for the increase in silver content. This justification may be in the form of a predicate device which contains the same or greater silver content in the same form (i.e., metallic silver). Please also include an assessment of the toxicological risk of silver in your device, including the potential for toxicity given the potential maximum dose, NOAEL, LOAEL, LD50, etc.

Response to FDA Comment 2:

(1) The discussion of differences in silver content has been added to "Section 12: Substantial Equivalency Discussions" in details, as well as to "Section 05: 510K Summary" in less details.
(2) The discussion of toxicological risks has been added to Section 11.7

FDA Comment 3:

You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.
b. We suggest providing, for each reagent, known published toxicological information.
c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits

Response to FDA Comment 3:

(a) COA and MSDS are added in this supplemental submission
(b) Known published toxicological information are added and discussed in Section 11.7
(c) Quantitative analytical evaluation, including method and detection limit are added to Section 11.7

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Comment 4:

You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

Response to FDA Comment 4:

(a) Results for three different lots, both initial and ages samples, have been added to Section 14 and Section 18
(b) Full test reports have been included in this supplemental submission
(c) Justification has been added following each test in Section 18.
(d) Silver release test has been re-performed following FDA suggestions. The results are summarized in Section 18.8. Test report is included in this supplemental.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

FDA Comment 5:

With regards to your antibacterial activity testing:

a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Response to FDA Comment 5:

(a) Clarification has been added to Section 18.6, 3rd paragraph, to clarify "This communication was NOT related to this subject device, but was an FDA general advice on conducting antibacterial testing on any type of antibacterial dressing." FDA email is included in this supplemental submission for your reference.
(b) Summary and labeling have been revised
(c) The information for initial and two year time points has been added to Section 14. Test reports are included in this supplemental submission.
(d) Rational for choose method 1 in calculation has been added to Section 18.6.4
(e) Test report has been revised with clear step (Section 10 of the report) and included in this supplemental submission. Please also see test methodology in the first paragraph of Section 18.6.2.
(f) The confusing parts have been removed from the revised antibacterial test report.
(g) A discussion of this reduction has been added to Section 18.6.4

FDA Comment 6:

With regard to your shelf life:

a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

Response to FDA Comment 6:

(a) Added to Section 14
(b) Test reports has been included in this supplemental submission

FDA Comment 7:

You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

Response to FDA Comment 7:

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Release criteria for each variants are added to Section 11.3. For Variants 2, 3,4, there is only additional size criteria and criteria for adhesive strength. Test results for adhesive strength are provided in Section 18.9

FDA Comment 8:

With regards to your labeling:

a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

b. Per the discussion above regarding the role of silver, we believe it is important to emphasize that silver is present only as a preservative for the dressing. Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

c. You state in your User Manual that the device maintains a moist environment "to accelerate healing process." This statement implies that the dressing actively promotes wound healing, which we believe to be a new intended use of this device. We would therefore require that this statement be substantiated by clinical data as part of a PMA submission for a Class III device. Accordingly, please remove this statement.

d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However, you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing

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over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

e. You present an "In vitro Study Results" section in your package labeling that details the biocompatibility and antibacterial effectiveness testing that has been performed on your device. In addition, your Instructions for Use contains an "Adverse Reactions" section that similarly discusses your biocompatibility testing. However, we believe this text implies that additional performance testing has been conducted beyond biocompatibility and performance testing needed for 510(k) clearance when such testing has not been performed. Therefore, please remove this section.
f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.
g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."
h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.
i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

Response to FDA Comment 8:

Labeling has been revised to address all the above FDA concerns

List of Documents included in this supplemental submission:

001_Response to K141619 Deficiency
002_Section 04_Indications for Use
003_Section 05_510k Summary Re2
004_Section 11_Device Description RE2
005_Section 12_Substantial Equivalence Discussion RE
006_Section 13_Labeling RE2
007_Section 14_Steriliy and Shelf Life Re
008_Section 18_Performance_Testing_BENCH RE
009_COA of AMPTS
010_COA of MTES
011_MSDS of Silver Solution
012_MSDS of AMPTS
013_MSDS of MTES
014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003
017_Test Report on Total Silver Aging Samples
018_Test Report on Silver Release Profile

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019_Revised Report on Antibacterial Testing
020_Antibacterial Test Report for Control Samples (No Silver)
021_Anticle on toxicity of silver compound
022_Email Communication with FDA

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen Charles Shen

Charles Shen, Official Correspondent
Date: January 10, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S002, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

"With regards to your intended use:

a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary. "

Response to FDA Comment 1:

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(2) The discussion of toxicological risks has been added to Section 11.7

FDA Comment 3:

You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.
b. We suggest providing, for each reagent, known published toxicological information.
c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits

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(a) COA and MSDS are added in this supplemental submission
(b) Known published toxicological information are added and discussed in Section 11.7
(c) Quantitative analytical evaluation, including method and detection limit are added to Section 11.7

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FDA Comment 4:

You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

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(b) Full test reports have been included in this supplemental submission
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(d) Silver release test has been re-performed following FDA suggestions. The results are summarized in Section 18.8. Test report is included in this supplemental.

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a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

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Response to FDA Comment 5:

(a) Clarification has been added to Section 18.6, 3rd paragraph, to clarify "This communication was NOT related to this subject device, but was an FDA general advice on conducting antibacterial testing on any type of antibacterial dressing." FDA email is included in this supplemental submission for your reference.
(b) Summary and labeling have been revised
(c) The information for initial and two year time points has been added to Section 14. Test reports are included in this supplemental submission.
(d) Rational for choose method 1 in calculation has been added to Section 18.6.4
(e) Test report has been revised with clear step (Section 10 of the report) and included in this supplemental submission. Please also see test methodology in the first paragraph of Section 18.6.2.
(f) The confusing parts have been removed from the revised antibacterial test report.
(g) A discussion of this reduction has been added to Section 18.6.4

FDA Comment 6:

With regard to your shelf life:

a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

Response to FDA Comment 6:

(a) Added to Section 14
(b) Test reports has been included in this supplemental submission

FDA Comment 7:

You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

Response to FDA Comment 7:

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Release criteria for each variants are added to Section 11.3. For Variants 2, 3,4, there is only additional size criteria and criteria for adhesive strength. Test results for adhesive strength are provided in Section 18.9

FDA Comment 8:

With regards to your labeling:

a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

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c. You state in your User Manual that the device maintains a moist environment "to accelerate healing process." This statement implies that the dressing actively promotes wound healing, which we believe to be a new intended use of this device. We would therefore require that this statement be substantiated by clinical data as part of a PMA submission for a Class III device. Accordingly, please remove this statement.

d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However, you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing

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over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

e. You present an "In vitro Study Results" section in your package labeling that details the biocompatibility and antibacterial effectiveness testing that has been performed on your device. In addition, your Instructions for Use contains an "Adverse Reactions" section that similarly discusses your biocompatibility testing. However, we believe this text implies that additional performance testing has been conducted beyond biocompatibility and performance testing needed for 510(k) clearance when such testing has not been performed. Therefore, please remove this section.
f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.
g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."
h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.
i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

Response to FDA Comment 8:

Labeling has been revised to address all the above FDA concerns

List of Documents included in this supplemental submission:

001_Response to K141619 Deficiency
002_Section 04_Indications for Use
003_Section 05_510k Summary Re2
004_Section 11_Device Description RE2
005_Section 12_Substantial Equivalence Discussion RE
006_Section 13_Labeling RE2
007_Section 14_Steriliy and Shelf Life Re
008_Section 18_Performance_Testing_BENCH RE
009_COA of AMPTS
010_COA of MTES
011_MSDS of Silver Solution
012_MSDS of AMPTS
013_MSDS of MTES
014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003
017_Test Report on Total Silver Aging Samples
018_Test Report on Silver Release Profile

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019_Revised Report on Antibacterial Testing
020_Antibacterial Test Report for Control Samples (No Silver)
021_Anticle on toxicity of silver compound
022_Email Communication with FDA

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles Shen, Official Correspondent
Date: January 10, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141619

Device Name

Luofucon Silver Foam Dressing

Indications for Use *(Describe)*

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

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Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

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Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver Foam dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

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Section 5: 510(K) Summary: Prescription

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 8
11.4 Summary of Test Results 11
11.5 List of All Materials Used 12
11.6 Manufacturing Process 13
11.7 Discussion of Toxicological Properties of Reagents Used in Manufacture Process 15
11.8 Silver Compound Used in the Products and Silver Particle Size 16
11.9 Bonding Between Silver Particles and Silver Leachability 17
11.10 Antimicrobial Activity Spectrum (Profile) 22
11.11 Minimum Effective Concentration 22
11.12 Likely Silver Antibacterial Mechanism 23

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11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

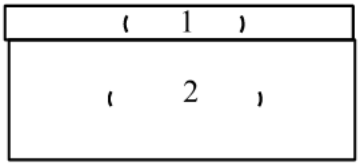
The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2, Table 11.5).

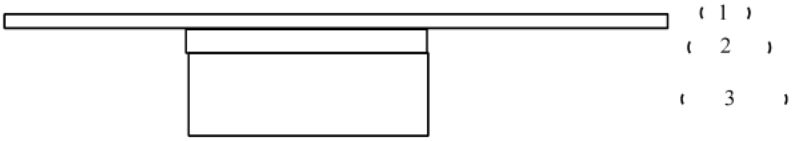
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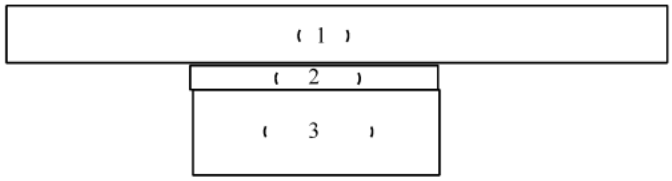
Illustrative drawing of the second variant: (1)) Thin polyurethane backing layer for cosmetic purpose (2) Thick polyurethane wound contacting layer

A third adhesive variant, bordered PU backing with adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.3, Table 11.5).



Illustrative drawing of the third variant: (1) Thin PET layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.4, Table 11.5).



Illustrative drawing of the fourth variant: (1) Non woven layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

For the third and fourth variants, the adhesive is composed of 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

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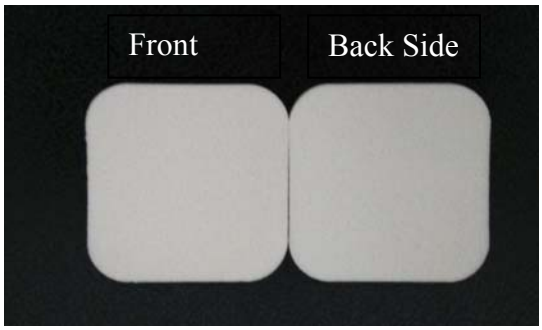
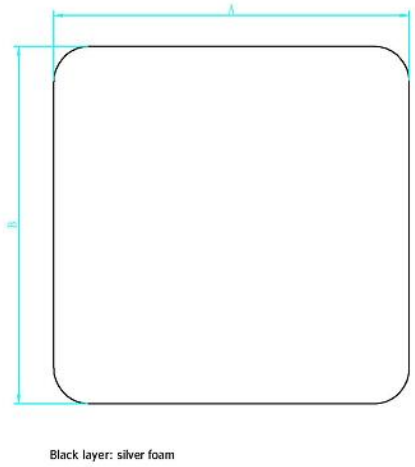
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Section 11: Device Description

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below. Secondary layer information are summarized in Table 11.5.

Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

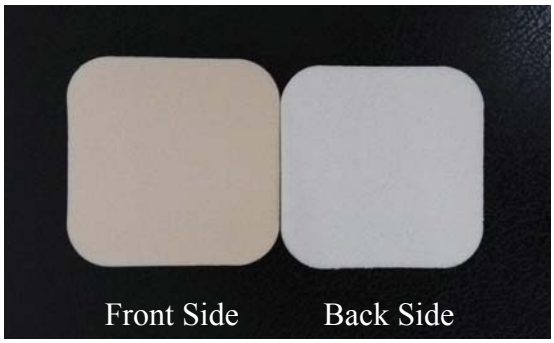
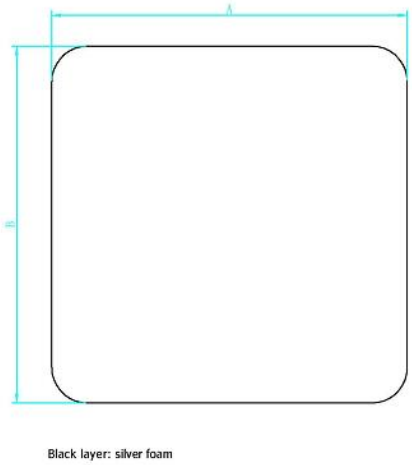
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

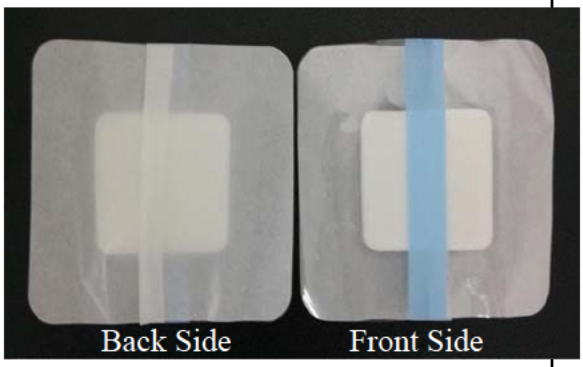
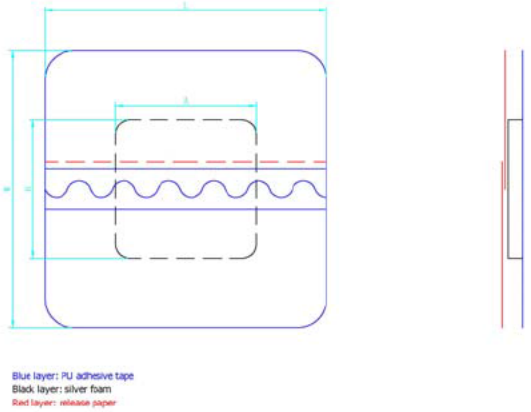
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

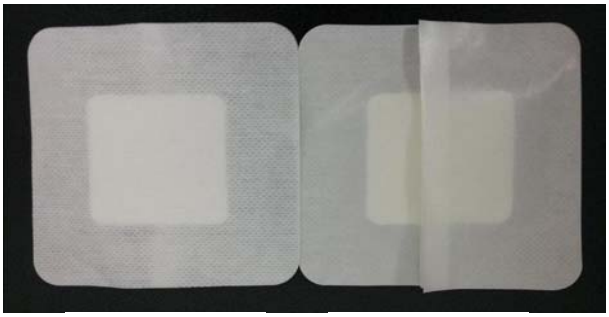
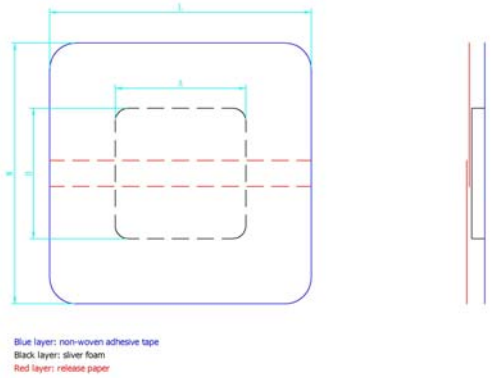
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.5: Secondary Layer Information Summary

Variant	Variant	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Packaging information is listed below:

Immediate Packaging: Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging: Paper Box
Outer Packaging: Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.6 to Table 11.9, for the Variants 1-4. The biological specifications are shown in Table 11.10.

Table 11.6: Physical Specification of Luofucon Silver Foam Dressing, First Variant

Test items	**Specification**	**Test Method [a]**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying
pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from

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Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.7: Physical Specification of Luofucon Silver Foam Dressing, Second Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method
Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.8: Physical Specification of Luofucon Silver Foam Dressing, Third Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
PET Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
PET Layer	Seal Strength	Shift by less than 2.5 mm	British Pharmacopoeia 1993 Appendix XXH Test 1
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method

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Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.9: Physical Specification of Luofucon Silver Foam Dressing, Fourth Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Non Woven Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Non Woven Layer	Seal Strength	Shift by less than 2.5 mm	British Pharmacopoeia 1993 Appendix XX H Test 1
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method
Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

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The biological specifications are shown in Table 11.10.

Table 11.10 Biological Specifications for Variants 1-4.

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201107001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.11 and 11.12.

Test results of additional lots and additional variants can be found in Section 18.

Table 11.11: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201107001, size 100 mm x 100 mm x 3 mm)

Test items	**Specification**	**Test Results**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Conform
Density	0.09-0.18 g/cm^3	0.112 gram/cm^3
Free Swell Absorption	≥10.0 g/g	12.6 g/g
Loss on Drying	≤6%	3.11%
pH	4.0～9.0	4.47

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Silver Content [a]	3±1 µg/cm^3	3.1 µg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

[a:] Incoming Quality Control

Table 11.12: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. The samples tested are:

LOT	S201207002	S201207003	S201305001
Type	Silver Foam dressing (Variant 3)	Silver Foam Dressing (Variant 1)	Silver Foam Dressing (Variant 1)
Manufacture Date	2012.7.29	2012.7.30	2013.5.2
Size	150×150mm (100×100×5mm)	100×100×5mm	100×100×3mm
Extraction Volume	75 mL	75 mL	45 mL

One piece of silver foam dressing in the different sizes and thickness mentioned in above table was used and immersed in simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, and for 48, and 72 hours
Extraction temperature: 37 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by validated internal FAB test procedure.

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The test results are summarized in the Table 18.11 below. Daily Leachable and Total Leachable are the actual detected silver leached from the foam dressings, as the experimental condition above states. % of Total Silver is calculated using a nominal silver amount of 3 μg/ cm^3. Therefore, 100 x 100 x 5 mm foam contains 150 μg silver, and 100 x 100 x 3 mm foam contains 90 μg silver.

The leachables are calculated as both daily leachable, which is the leached silver amount within 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

Table 1: Silver Release Study of LOT S201207002

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (μg)	Daily Release as % of Total Silver[a]	Total Release (μg)	Total Release as % of Total Silver[a]
24	1.0722	75	80.42	53.61%	80.42	53.61%
48	0.3884	75	29.13	19.42%	109.55	73.03%
72	0.1636	75	12.27	8.18%	121.82	81.21%

[a]: 150×150mm (100×100×5mm) silver foam contains about 150μg silver, and was use in the calculation.

Table 2: Silver Release Study of LOT S201207003

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (μg)	Daily Release as % of Total Silver[b]	Total Release (μg)	Total Release as % of Total Silver[b]
24	1.1108	75	83.31	55.54%	83.31	55.54%
48	0.4057	75	30.43	20.29%	113.74	75.83%
72	0.1871	75	14.03	9.36%	127.77	85.18%

[b]: 100×100×5mm silver foam contains about 150μg silver, and was use in the calculation.

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Table 3: Silver Release Study of LOT S201305001

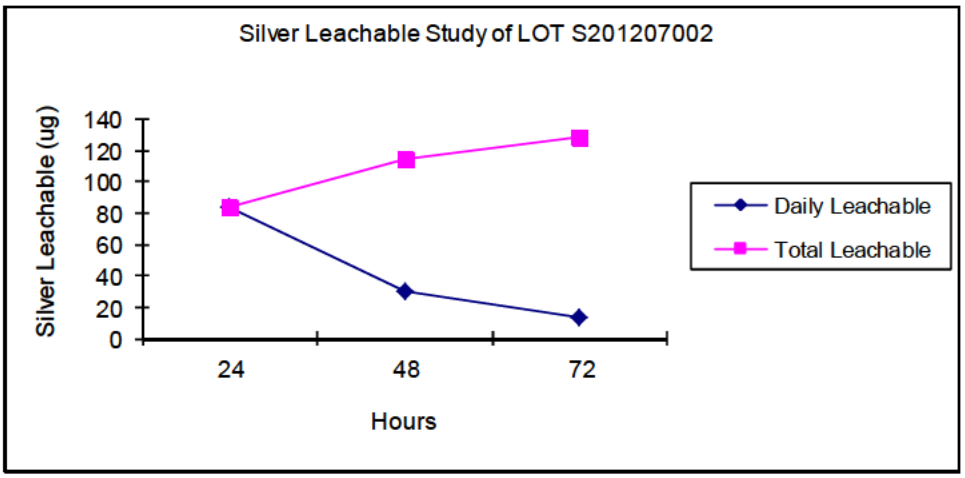
Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (µg)	Daily Release as % of Total Silver[c]	Total Release (µg)	Total Release as % of Total Silver[c]
24	0.9874	45	44.43	49.37%	44.43	49.37%
48	0.3529	45	15.88	17.65%	60.31	67.02%
72	0.1370	45	6.17	6.85%	66.48	73.87%

[c]: 100×100×3mm silver foam contains about 90µg silver, and was use in the calculation.

Under this simulated condition, LUOFUCON Silver Foam Dressing leaches maximum 55.54% of the total silver during the first 24 hours, and leaches maximum 20.29%, and 9.36% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours maximum 85.18% of the total silver was leached out.

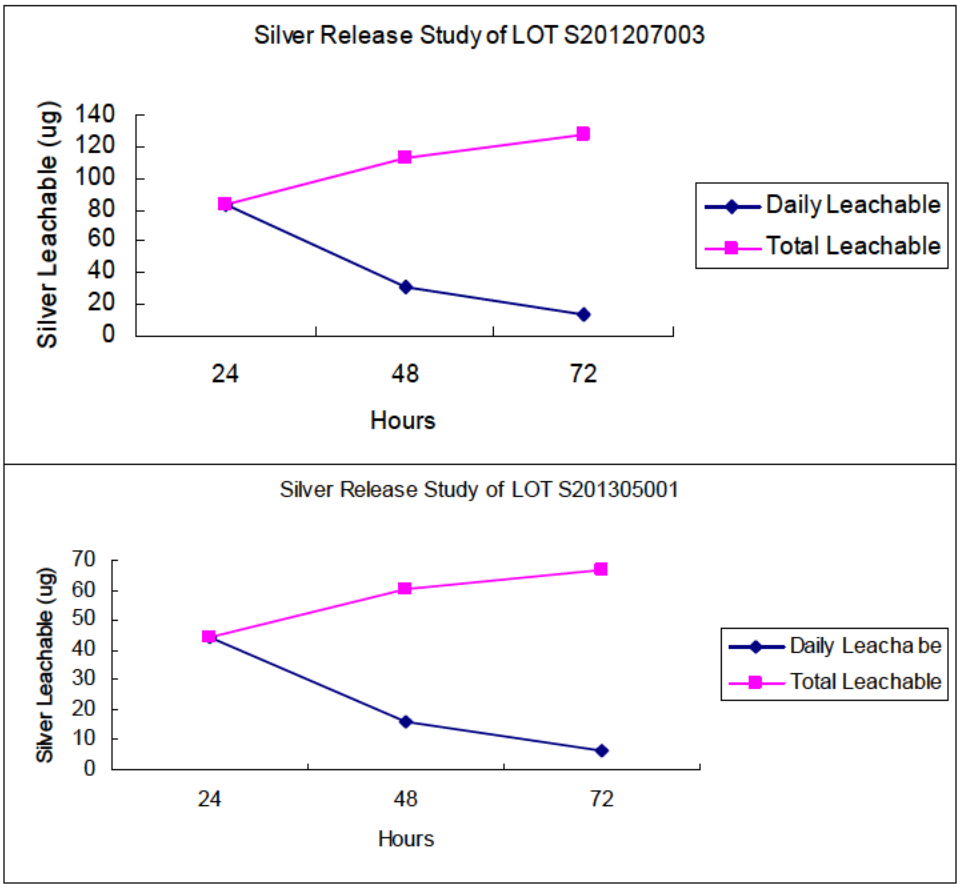
Since the nominal concentration of silver 3±1 µg/cm^3, after three days of recommended usage duration, at least 85.18% of silver is released, equivalent to at least 2.64 µg/cm^3. This number, 2.64 µg/cm^3, will be converted to µg per device and shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, in theory might cause much less skin discoloration effect.



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Details of this experiment can be found in **Section 18**

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11.10 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.11 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.12 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 12: Substantial Equivalence Discussion

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

Table 12.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same

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Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains about 3μg/cm^3 silver, equivalent to about 27 ppm when the density is about 0.11 g/cm^3. The predicate device contains about 79 ppm silver. According to a recent research (Particle and Fibre Toxicology, 2010, 7:20), the NOEAL and LOEAL of silver are 30 and 125 ppm respectively (Included in this supplemental submission). Therefore the silver content in the subject device is less than the predicate device, and is less than what NOEAL and LOEAL allow. Silver content at this level is not going to raise any safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 12.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 12.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection

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Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 13: Proposed Labeling

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

Rx Only
Version: A/0

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure containing silver particles which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. The total maximum amount of silver partilces is 4ug/cm^3. The silver is present as a preservative to inhibit bacterial colonization within the dressing. LUOFUCON® Silver Foam Dressing has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.
The **Silver Foam Dressing with PU Backing** consists of silver foam and breathable polyurethane film for waterproof. The **Bordered Silver Foam Dressing** is silver foam on a PU/PET film or non-woven coated with acrylic adhesive and extends to act as a border adhesive to allow fixation without secondary dressing or fixation bandage.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers(venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns(1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria:

Proven Antibacterial Effectiveness

Bacterial	72 Hour Log Reduction
Staphylococcus aureus (ATCC 6538)	4 Log
Streptococcus pyogenes (ATCC 19615)	4 Log
Enterococcus faecalis (ATCC 29212)	4 Log
Escherlchia coli (ATCC 8739)	4 Log
Klesiella pneumonlae (ATCC 4352)	4 Log
Pseudomonas aeruginosa (ATCC 9027)	4 Log

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Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. The dressing should be left on the skin for no more than three days.

Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Specifications (Including 3mm and 5mm)

Foam or With PU Backing	PU or Non-woven Adhesive
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
125×100	150×150(100×100)
150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 1:



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Variant 2:



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Variant 3:



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Variant 4:



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13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

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Variant 1



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Variant 2:



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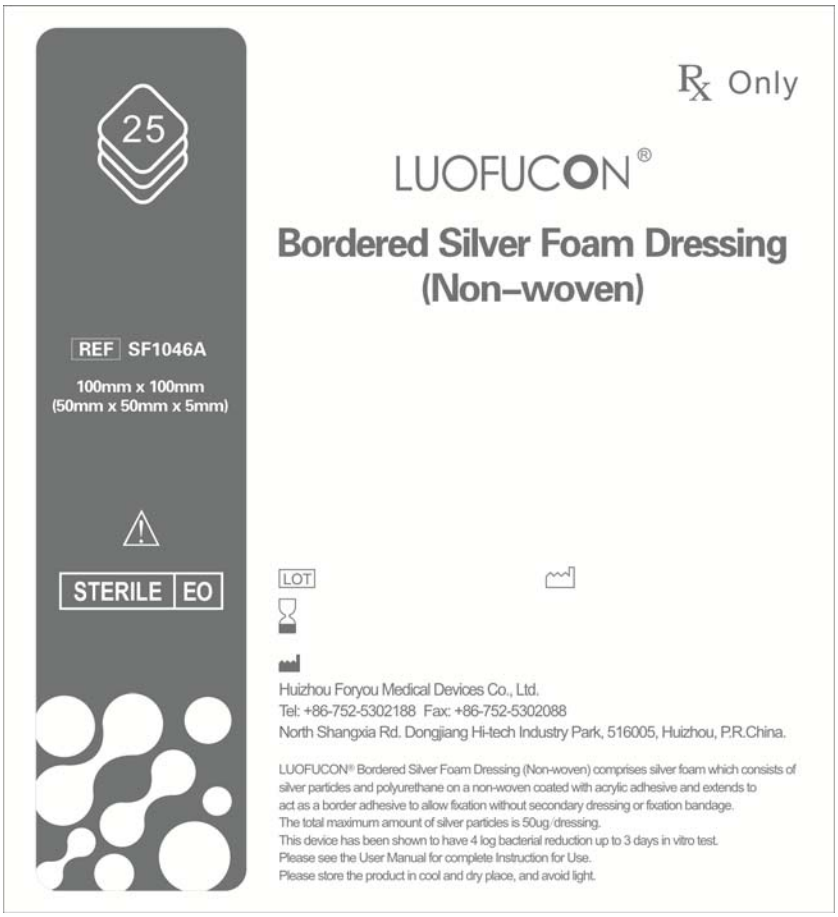
Variant 3:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 4:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 14: Sterility and Shelf Life

Luofucon Silver Foam Dressing is sold directly to users after EtO sterilization validation to ISO 11135-1:2007, the sterilization method to be used is ethylene oxide with overkill approach. The details are the following:

14.1 Sterility Validation

The ethylene oxide method used to sterilize our "Luofucon Silver Foam Dressing" was validated following ISO 11135-1:2007. The method validation report can be found in **Appendix 1.**

Foam dressing without silver deposition was used to validate the procedure. Because of the general antibacterial activity of the silver ion, foam dressing without silver deposition has higher level of micro-organisms, thus represents the worst case scenario.

14.1.1 Reference of Standard: ISO-11135-1:2007

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: Yes. Foam dressing prior to silver deposition was used to validate the procedure. Justification: Foam dressing without silver is more difficult to sterilize (because silver itself is an antibacterial agent) thus represent the worst case scenario.

The name and address of test laboratory: In house

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Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	Yes
3	Terms and definitions	Yes
4	Quality management systems	Yes
5	Sterilizing agent characterization	Yes
6	Process and equipment characterization	Yes
7	Product definition	Yes
8	Process definition	Yes
9	Validation	Yes
10	Routine monitoring and control	Yes
11	Product release from sterilization	Yes
12	Maintaining process effectiveness	Yes

14.1.2. Validation Method

Sterilization method was validated following ISO-11135-1:2007. Ethylene oxide is used as the sterilization method. The method validation report is in Appendix 1.

Overkill approach (Half-cycle approach) is used following Annex B of the standard. A total of three consecutive experiments resulting in total inactivation of the biological indicators were performed in order to confirm the minimum exposure time. The specified exposure time doubles this minimum time. A cycle of short duration was also run to demonstrate the adequacy of the recovery technique.

Validation includes installation qualification, operational qualification, and process qualification.

Installation qualification (IQ) demonstrated that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

Operational qualification (OQ) demonstrated that the installed equipment is capable of delivering the specified process within defined tolerances.

The microbiological PQ was performed in the production chamber using defined process parameters selected to deliver less lethality than the specified sterilization process. The results demonstrated that, on application of the sterilization process, the specified requirements for sterility are met.

Physical PQ included a minimum of three planned qualification runs in which all the specified acceptance criteria are met. The results demonstrated reproducibility of the process and the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specifications.

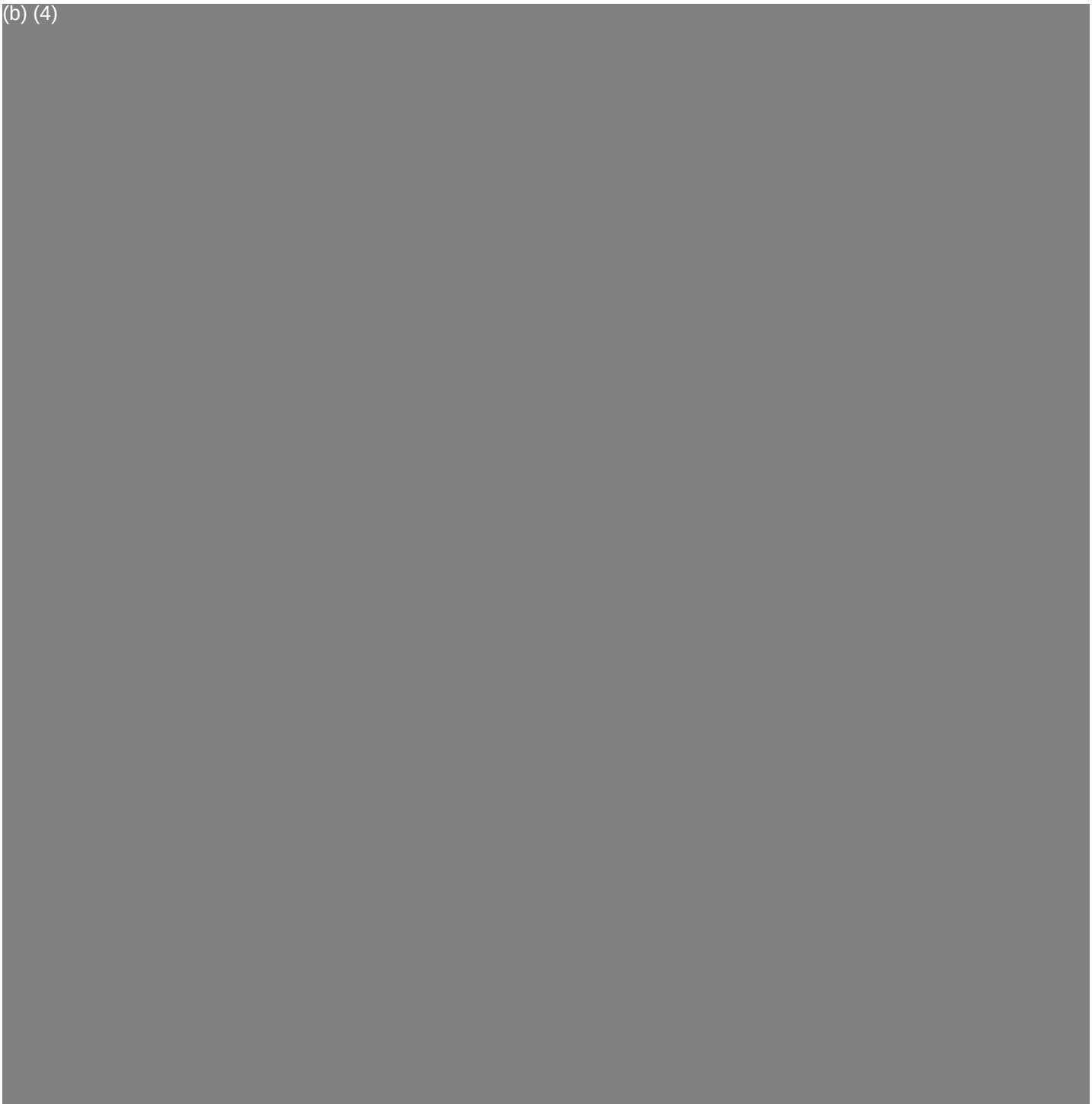
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Section 14: Sterility and Shelf

The validated sterilization parameters are the following:

(b) (4)



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(b) (4)

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14.1.4. SAL Level

The SAL level was found to be NMT 10^{-6} during our experiments.

14.2 Product Packaging

Luofucon Silver Foam Dressing is packaged in single use flexible package. Packages are supplied as preformed sterile barrier systems where all the seals have been formed except at the bottom. This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. A sealant layer is applied to allow heat-sealing of the two layers together.

The material, sterile barrier system, and product packaging are designed following the suggestions provided by ISO-11607-1. They have been proven to maintain sterility of terminally sterilized medical devices during storage, transportation, and distribution, until the point of use.

Table 14.3: Summary of packaging information involved in this submission

Immediate Packaging	Enforced paper- Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging	Paper Box
Outer Packaging	Corrugated Board Carton

14.3 Shelf Life Determination

The shelf life was determined by real time aging for products stored under ambient conditions. The proposed shelf life is two years.

14.3.1 Physical Properties

For real time aging test, products were stored under 25 ºC and 60% RH. Representative test results are summarized for Lot No.: S201107001; size100×100×3 mm; production date: July 12, 2011.

Both performance properties and packaging integrity were evaluated for up to two years.

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Physical properties were tested against product specifications as detailed in Section 11. All test results met specification and the results are summarized in the Table 14.4 to Table 14.6 below for three representative lots. Only average results are summarized here. For individual sample results, please see attached real time aging test report.

Table14.4: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201107001)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×3±0.3mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.112	0.108	0.113
Absorbance	≥10g/g	12.6	12.3	11.2
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.47	4.44	4.56
Loss On Drying	≤6.0%	3.1%	4.1%	4.4%

Table14.5: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201207002)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×5±0.5mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.113	0.108	0.110
Absorbance	≥10g/g	12.5	12.2	12.0
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.82	4.84	4.89
Loss On Drying	≤6.0%	3.1%	3.3%	3.9%

Table14.6: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201207003)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×5±0.5mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.106	0.111	0.108
Absorbance	≥10g/g	12.6	12.4	12.1
Sterility	Zero positive	Pass	Pass	Pass

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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pH	4.0-9.0	4.74	4.82	4.86
Loss On Drying	≤6.0%	3.4%	3.7%	3.9%

The silver contents of our device were tested and summarized in separate report (see attached test report No SF-HL2). Shown below in Table 14.7 to Table 14.9 are results for three lots of samples in initial, one year, and two years time points.

Table 14.7 Silver content test results, Initial time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201207002	0.700	2.80	3.02
	0.803	3.21	
	0.763	3.05	
S201207003	0.747	2.99	2.92
	0.716	2.86	
	0.728	2.91	
S201305001	0.486	3.24	3.09
	0.462	3.07	
	0.446	2.97	

Table 14.8: Silver content test results, one year time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201305001	0.401	2.67	2.81
	0.413	2.75	
	0.450	3.00	

Table14.9: Silver content test results, two year time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201207002	0.744	2.97	2.96
	0.713	2.85	
	0.766	3.06	
S201207003	0.707	2.83	2.98
	0.751	3.00	
	0.783	3.13	

These results show that the silver contents met the product specification of 3±1 µg/cm^{3}for at least two years.

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14.3.2 Antibacterial Properties

Antibacterial properties were tested following standard AATCC-100:2004. Detailed test procedures are described in Section 18.7.2. In brief, an inoculum of the chosen challenge organism is absorbed into the test article and allowed to incubate for approximately 24 hours. The surviving challenge organisms are enumerated and compared to an untreated control.

Total of six bacteria (three Gram positive and three Gram negative) were tested:

Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 19615)
Enterococcus faecalis (ATCC 29212)
Escherichia coli (ATCC 8739)
Pseudomonas aeruginosa (ATCC 9027)
Klebsiella pneumoniae (ATCC 4352)

The antibacterial results after two years of ambient storage are presented in Table 14.5. The test was performed by Guangdong Detection Center of Microbiology, as an independent verification by third party.

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Table 14.11: Silver Foam Sample: Antibacterial activity results at Two Year Time Point. Size 100 x 100 x 3mm. The two year time point date was tested on Lot S201107001, manufacture date: July 12, 2011, test date: Sept 2013.

Bacterial	**Staphylococcus aureus ATCC 6538**			**Streptococcus pyogenes ATCC 19615**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	4.8×10^5/mL			4.7×10^5/mL		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28
Day-3 Inoculum Concentration	4.8×10^5			4.7×10^5		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28

Bacterial	**Enterococcus faecalis ATCC 29212**			**Escherlchia coli ATCC 8739**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.3×10^5/mL			5.2×10^5/mL		
Initial Contact time	2.1×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.0×10^6	2.0×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.32	>4.30	>4.32	>4.30	>4.30	>4.30
Day-3 Inoculum Concentration	5.3×10^5			5.2×10^5		
Initial Contact time	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.32	>4.3	>4.32	>4.30	>4.30	>4.30

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Bacterial	**Klesiella pneumonlae ATCC 4352**			**Pseudomonas aeruginosa ATCC 9027**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.0×10^5/mL			5.3×10^5/mL		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32
Day-3 Inoculum Concentration	5.0×10^5			5.3×10^5		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32

[a]: Inoculum Concentration is presented as CFU/ 1.0ml, while 4.0 mL was actually used each time to give 1.0-2.0 x 10^6 CFU.

These results show that the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The summary results of antibacterial efficacy for additional two lots of aged samples are shown Table 14.12 and Table 14.13 below: For more details of the results, please see attached test report on aged samples.

Table 14.12: Summary of Antibacterial Results for Lot S201207002 over Two Years

Time point	Contact time	Average CFU (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero	0h Untreated	1.30×10^6	1.85×10^6	1.67×10^6	3.2×10^6	2.8×10^6	2.10×10^6
	0h Treated	1.25×10^6	1.88×10^6	1.57×10^6	2.7×10^6	2.8×10^6	1.89×10^6
	24h Treated	<100	<100	<100	<100	<100	<100
	72h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
1-year	0h Untreated	1.60×10^6	1.63×10^6	1.07×10^6	1.18×10^6	2.42×10^6	1.50×10^6
	0 h Treated	1.56×10^6	1.59×10^6	1.00×10^6	1.26×10^6	2.32×10^6	1.53×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
2-year	0 h Untreated	1.62×10^6	2.30×10^6	1.68×10^6	1.77×10^6	1.21×10^6	2.09×10^6
	0 h Treated	1.57×10^6	2.19×10^6	1.55×10^6	1.86×10^6	1.15×10^6	2.13×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 14.13: Summary of Antibacterial Results for Lot S201207003 over Two Years

Time point	Contact time	Average CFU (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero	0 h Untreated	1.19×10^6	1.87×10^6	1.46×10^6	2.05×10^6	1.96×10^6	1.57×10^6
	0 h Treated	1.21×10^6	1.77×10^6	1.42×10^6	2.00×10^6	1.72×10^6	1.52×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
1-year	0 h Untreated	2.07×10^6	1.41×10^6	1.45×10^6	1.83×10^6	1.18×10^6	3.4×10^6
	0 h Treated	2.01×10^6	1.34×10^6	1.36×10^6	1.74×10^6	1.12×10^6	2.8×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
2-year	0 h Untreated	1.00×10^6	1.71×10^6	1.33×10^6	1.65×10^6	2.15×10^6	1.07×10^6
	0h Treated	1.03×10^6	1.59×10^6	1.38×10^6	1.61×10^6	2.08×10^6	1.09×10^6
	24h Treated	<100	<100	<100	<100	<100	<100
	72h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

These results show that for all three representative lots over two years, the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

14.3.3 Packaging Integrity

Packaging integrity were tested for tensile strength (following suggestions by ASTM F88), dye penetration (following suggestions by ASTM F1929-98: 2004), and sterility. The results are summarized in Table 14.14 to Table 14.16 for three representative lots. All pre-defined criteria were met for up to two years. Please see attached test reports on aged samples for more details.

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Table14.14: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201107001

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.12	2.98	2.90
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

Table14.15: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201207002

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	4.01	3.96	3.75
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

Table14.16: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201207003

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.99	3.94	3.73
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

14.3.3 Conclusion for Aging Tests

Based on the above results, Luofucon Silver Foam Dressing is stable for up to two year under normal storage conditions. The product shelf life is designated as two years on the labeling.

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Section 18: Performance Testing – Bench

This section contains the bench performance testing results for the Luofucon Silver Foam Dressing described in this submission. The tests including the following:

Section 18.1 Density 2
Section 18.1.1 Experimental: 2
Section 18.1.2 Results and Discussions: 2
Section 18.1.3 Justification for Application of the Data to All Four Variants: 2
Section 18.2 Absorbency Test: Free Swell Absorption Capacity 4
Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002 4
Section 18.2.2 Experimental: 5
Section 18.2.3 Results and Discussions: 5
Section 18.2.3 Justification for Application of the Data to All Four Variants: 6
Section 18.3: Loss on Drying 7
Section 18.3.1: Reference to Standard USP 34 General Chapter <731> 7
Section 18.3.2: Experimental 7
Section 18.3.3: Results and Discussions 8
Section 18.3.3 Justification for Application of the Data to All Four Variants: 8
Section 18.4: pH Value 9
Section 18.4.1: Reference to Standard USP<791> 9
Section 18.4.2: Experimental 9
Section 18.4.3: Results and Discussions: 10
Section 18.4.4 Justification for Application of the Data to All Four Variants: 10
Section 18.5: Silver Content 11
Section 18.5.1: Experimental 11
Section 18.5.3: Results and Discussions: 13
Section 18.5.4 Justification for Application of the Data to All Four Variants: 13
Section 18.6: Antibacterial Activity 15
Section 18.6.1: Reference to the AATCC 100-2004 15
Section 18.6.2: Experimental 16
Section 18.6.3: Testing Results 21
Section 18.6.4: Discussion of Testing Results 24
Section 18.7.1: Experimental 27
Section 18.7.2: Results 28
Section 18.7.3: Discussions and Conclusion 30
Section 18.8: Silver Leachablity Study 31
Section 18.8.1: Experimental 31
Section 18.8.2: Results and Discussions: 32
Section 18.9: Adhesive Strength 35
Section 18.9.1: Experimental 35
Section 18.9.2: Results and Discussions: 35

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Section 18.1 Density

Density of the immediate patient contact layer of the device is an important parameter used in product quality control.

Section 18.1.1 Experimental:

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The weight of the material was determined by calibrated balance. The width, thickness, and length of the sample were measured by calibrated ruler. Density was calculated as gram/cm^3

Acceptance Criteria: 0.09-0.18 g/cm^3

Section 18.1.2 Results and Discussions:

Shown below in Table 18.1 are exemplary density results for the three lots mentioned above.

Table18.1: Exemplary Density Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average	%RSD
S201107001	0.109	0.114	0.113	0.112	2.4%
S201207002	0.112	0.109	0.117	0.113	3.6%
S201207003	0.105	0.111	0.102	0.106	4.3%

In this exemplary measurement, average densities are 0.112, 0.113, and 0.106 g/m^3, and %RSD are 2.4, 3.6, and 4.3, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of 0.09 – 0.18 g/cm^3.

Section 18.1.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;

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- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or securing purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Density of only the skin contact layer of device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.2 Absorbency Test: Free Swell Absorption Capacity

Absorptive capacity of the immediate patient contact layer of the device is an important feature to assess the performance of dressings, especially these used on moderately to heavily exuding wounds.

The test was performed following BS EN 13726-1:2002: Test Methods for Primary Wound Dressings-Part 1: Aspects of absorbency. Section 3.2 of the standard: Test for Absorbency: Free Swell Absorption Capacity was chosen.

This chosen procedure is appropriate for dressings which stays physically intact and reaches maximum absorptive capacity within 30 min under the test conditions. This procedure is suitable for most types of foam dressings

Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any options the standard provides: Only Section 3.2: Test for Absorbency: Free Swell Absorption Capacity was chosen. The other test procedures (Sections 3.3 to 3.7) do not apply based on the nature of our product.

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Tested In-house

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Terms and Definitions	Yes
3	Test Methods for Absorbency	Yes
3.1	Test Conditions	Yes
3.2	Free Swell Absorption Capacity	Yes
3.3	Fluid Handling Capacity	Not Apply
3.4	Fluid Affinity of Amorphous Hydrogel Dressings	Not Apply
3.5	Gelling Characteristics	Not Apply

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3.7	Dispersion Characteristics	Not Apply
3.8	Dispersion/Solubility of Hydrogel Dressings	Not Apply

Section 18.2.2 Experimental:

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The tests were carried out at at (21 ± 2) °C and relative humidity of 60 % RH ± 15 % RH.

Test solution was prepared by dissolving appropriate amount of sodium chloride and calcium chloride dihydrate in deionised water to make a solution contains 142 mmol of sodium ions and 2,5 mmol of calcium ions as the chloride salts. This solution has an ionic composition comparable to human serum or wound exudate.

A single sample was cut to 5cm x 5cm, weighed and placed in a Petri dish.

Test solution corresponding to 40 times the mass of sample was pre-warmed to (37±1) °C and added to the sample. The sample was then transferred to the oven and allowed to stand for 30 min at (37±1) °C.

The sample was suspended by forceps on one corner or by one end as appropriate, for 30 s before it was weighed.

The absorptive capacity was calculated as the average mass of solution retained per gram of sample.

Acceptance Criteria: ≥10.0g/g

Section 18.2.3 Results and Discussions:

Shown below in Table 18.2 are exemplary absorption capacity results for the three lots mentioned above.

Table18.2: Exemplary Absorption Capacity Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average (g/g)	%RSD
S201107001	11.91	12.80	13.22	12.64	5.3%
S201207002	12.51	12.19	12.68	12.46	2.0%
S201207003	12.13	12.07	13.51	12.57	6.5%

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In this exemplary measurement, average absorption capacities are 12.64, 12.46, and 12.57 g/g, and %RSD are 5.3, 2.0, and 6.5, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of free swell absorption ≥10.0g/g.

Section 18.2.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only the absorbency of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.3: Loss on Drying

Loss on Drying of the immediate patient contact layer of the device was tested following USP 34 General Chapter <731>: Loss on Drying

Section 18.3.1: Reference to Standard USP 34 General Chapter <731>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The Standard does not have sections	Loss on Drying	Yes

Section 18.3.2: Experimental

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The dressing was cut into 5mm x 5mm. About 1 gram was weighed. An appropriate glass-stoppered, shallow weighing bottle was dried for about 30 minutes under the same conditions to be employed in the determination and cooled to room temperature in a desiccator. The test specimen was placed in the bottle, replaced the cover, and the weight of the bottle and the contents were recorded accordingly. The loaded bottle was then placed in the drying chamber, the stopper was removed and was also left in the chamber. The drying lasted for three hours at 105 °C. Upon opening the chamber, bottle was closed promptly, and was allowed to cool to room temperature in a desiccator before weighing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Acceptance Criteria: ≤6%

Section 18.3.3: Results and Discussions

Shown below in Table 18.3 are exemplary loss on drying results for the three lots mentioned above.

Table18.3: Exemplary Loss on Drying Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average (%)	%RSD
S201107001	3.01%	3.14%	3.18%	3.11%	2.9%
S201207002	3.09%	3.14%	3.04%	3.09%	1.6%
S201207003	3.45%	3.60%	3.24%	3.43%	5.3%

In this exemplary measurement, average loss on drying are 3.11%, 3.09%, and 3.43%, and %RSD are 2.9, 1.6, and 5.3, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of ≤6%

Section 18.3.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only Loss on Drying property of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.4: pH Value

The dressing sample (immediate patient contact layer of the device) is leached in water and the pH value of the solution was tested following USP 34 General Chapter <791>: pH

Section 18.4.1: Reference to Standard USP<791>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The monograph does not contain any sections	pH	Yes

Section 18.4.2: Experimental

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The layer was cut into small pieces. About one gram was weighed to the nearest 0.01g, and 25mL of distilled water without carbon dioxide was added. The solution was then stirred at (37±1)℃ for 24h to get leaching solution. The pH was calibrated and pH value of the leaching solution was determined following USP 34 General Chapter <791>

Acceptance Criteria: pH value should be between 4.0 – 9.0.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.4.3: Results and Discussions:

Shown below in Table 18.4 are exemplary pH values for the three lots mentioned above.

Table18.4: Exemplary pH Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average	%RSD
S201107001	4.47	4.44	4.49	4.47	0.6%
S201207002	4.83	4.77	4.86	4.82	1.0%
S201207003	4.75	4.68	4.79	4.74	1.1%

In this exemplary measurement, average pH values are 4.47, 4.82, and 4.74, and %RSD are 0.6, 1.0, and 1.1, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of 4.0 – 9.0.

Section 18.4.4 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only pH property of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.5: Silver Content

Silver content in the silver foam dressing (immediate patient contact layer of the device) was measured by validated FAAS (flame atomic absorption spectrometry).

Section 18.5.1: Experimental

The following samples were tested:

- Lot S201305001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

Sample Preparation and Digestion:

(b) (4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Research

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Subchronic oral toxicity of silver nanoparticles

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Abstract

Background

The antibacterial effect of silver nanoparticles has resulted in their extensive applicat on in health, electronic, consumer, medicinal, pest cide, and home products; however, silver nanoparticles remain a controversial area of research with respect to their toxic ty in biolog cal and ecological systems.

Results

This study tested the oral toxic ty of silver nanoparticles (56 nm) over a period of 13 weeks (90 days) in F344 rats following Organizat on for Econom c Cooperation and Development (OECD) test guideline 408 and Good Laboratory Pract ces (GLP). Five-week-old rats, weighing about 99 g for the males and 92 g for the females, were divided into four 4 groups (10 rats in each group): veh cle control, low-dose (30 mg/kg), middle-dose (125 mg/kg), and high-dose (500 mg/kg). After 90 days of exposure, clinical chemistry, hematology, histopathology, and silver distribution were studied. There was a signif cant decrease ($P < 0.05$) in the body weight of male rats after 4 weeks of exposure, although there were no significant changes in food or water consumption during the study period. Significant dose-dependent changes were found in alkaline phosphatase and cholesterol for the male and female rats, indicating that exposure to more than 125 mg/kg of silver nanoparticles may result in slight liver damage. Histopatholog c examination revealed a higher incidence of bile-duct hyperplasia, with or without necrosis, fibrosis, and/or pigmentation, in treated animals. There was also a dose-dependent accumulation of silver in all tissues examined. A gender-related difference in the accumulation of silver was noted in the kidneys, w th a twofold increase in female k dneys compared to male kidneys.

Conclusions

The target organ for the silver nanoparticles was found to be the liver in both the male and female rats. A NOAEL (no observable adverse effect level) of 30 mg/kg and LOAEL (lowest observable adverse effect level) of 125 mg/kg are suggested from the present study.

Background

The antibacterial activity exhibited by silver in a range of studies [1-5] has resulted in the widespread use of silver nanoparticles in bedding, washing machines, water purification, toothpaste, shampoo and rinse, nipples and nursing bottles, fabrics, deodorants, filters, k tchen utensils, toys, and humidifiers [6,7], where the main body or inner surface of the product is mixed or coated with germ-resistant nano-silver to prevent the growth of fungi and bacteria. Despite such widespread use of silver-nanoparticle-containing products, subchron c and chronic toxicity data on silver nanopart cles remain rare. The lack of exposure data on silver nanopart cles in the workplace and silver nanoparticles released from consumer products or released into the environment makes it difficult to assess the risks of using these materials. Limited data have been reported for silver nanopart cles by inhalation and oral routes of exposure. The target organs for silver nanoparticles by subchronic inhalation are the lungs and liver in male and female rats [8]. This study suggested a NOAEL (no observable adverse effect level) of 100 μg/m^3.

A LOAEL (lowest observable adverse effect level) and NOAEL have been reported for a 28-day oral toxicity study using Sprague-Dawley rats to be 300 mg/kg and 30

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mg/kg, respectively [9]. In this study, F344 rats were exposed to silver nanoparticles following the Organization for Economic Cooperation and Development (OECD) test guideline 408 (OECD, 1998), using a 13-week repeated-oral-dose toxicity protocol. The study was conducted under OECD Good Laboratory Pract ces (GLP). Clinical chemistry, histopathology, and distribut on of silver nanoparticles were investigated in blood, lungs, kidneys, brain, liver, and other organs.

Materials and methods

Silver Nanoparticles

Silver nanoparticles (CAS No. 7440-22-4) were purchased from NAMATECH, Ltd. (Daejeon, Korea), and were at least 99.98% pure. Count median diameter and geometric standard deviation of silver nanopart cles in 0.5% aqueous carboxymethylcellulose (CMC, Sigma USA) analyzed by transmission electron microscopy were 56 nm and 1.46, respectively (Figure 1).

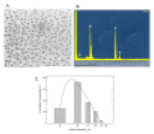


Figure 1. Transmission electron micrograph of silver nanoparticles and distribution of silver nanoparticles. The bar indicates 2 μm. A. Transmission electron micrograph of silver nanoparticles. B. Energy dispersive x-ray profile (silver nanoparticles on copper grid). C. Distribution of silver nanoparticles.

Transmission Electron Microscopy

The filters on which the silver nanoparticles in the 0.5% CMC were filtered were coated with carbon, mounted on an electron m croscope grid (200 mesh, Veco, Eerbeek, Holland), and visualized under a transmission electron microscope (TEM, Hitachi 7100). The diameters of 400 randomly selected part cles were measured at 50,000 × magnification, and the silver particles were analyzed using an energy-dispersive x-ray analyzer (EDX-200, Horiba, Japan) at an accelerating voltage of 75 kV.

Animals and Conditions

Four-week-old male and female, specific-pathogen free (SPF) Fisher 344 rats were purchased from Japan SLC Inc. (Japan) and acclimated for 7 days before starting the experiments. During the acclimation and experimental periods, the rats were housed in polycarbonate cages (maximum of 3 rats per cage) in a room with controlled temperature (22.2 ± 1.7°C) and humidity (48.4 ± 6.0%), and a 12-h light/dark cycle. The rats were fed a rodent diet (Harlan Teklad, USA) and filtered water *ad libitum*. The rats were div ded into 4 groups (10 rats in each group): vehicle control (0.5% carboxymethylcellulose, CMC), low-dose group (30 mg/kg/day), middle-dose group (125 mg/kg/day), and high-dose group (500 mg/kg/day). When the rats reached five weeks of age, they were exposed to silver nanopart cles following OECD test guideline 408 [10] by gavage for 13 weeks of repeated oral administration (dosing volumes were 10 ml/kg). Dose levels were selected based on previous observations in a 28-day oral toxicity study by Kim et al. [9]. The study was conducted under OECD Good Laboratory Pract ces.

Clinical Chemistry and Hematology

At the conclus on of the 13-wk experiment, the rats were 18 wks old. Before necropsy, food was withheld for 24 h and the rats were anesthetized w th CO_2 gas. Blood was then drawn from the abdominal aorta, collected in heparinized vacutainers, and analyzed for ALB (albumin), ALP (alkaline phosphatase), Ca (calcium), CHO (cholesterol), CRE (creatinine), gamma-GT (gamma-glutamyl transpeptidase), GLU (glucose), GOT (glutamic oxaloacetic transaminase), GPT (glutamic pyruv c transminase), IP (inorganic phosphorus), LDH (lactate dehydrogenase), MG (magnesium), TP (total protein), UA (uric ac d), BUN (blood urea nitrogen), TBIL (total bilirubin), CK (creatine phosphokinase), Na (sodium), K (potassium), Cl (chloride), TG (triglyceride), and A/G (ratio of albumin to globulin) using a b ochemical blood analyzer (Hitachi 7180, Hitachi, Japan). The blood was also analyzed for the WBC (white blood cell count), RBC (red blood cell count), Hb (hemoglobin concentration), HTC (hematocrits), MCV (mean corpuscular volume), MCH (mean corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), RDW (red cell distribut on width), PLT (platelet count), MPV (mean platelet volume), NE# (number of neutrophils), NE% (percent of neutrophils), LY# (number of lymphocytes), LY% percent of lymphocytes), MO# (number of monocytes), MO% (percent of monocytes), EO# (number of eosinophils), EO% (percent of eosinophils), BA# (number of basophils), and BA% (percent of basophils) using a blood cell counter (Hemavet 0950, CDC Tech., USA).

Organ Weights and Histopathology

After collecting blood samples, the rats were killed by cerv cal dislocation. Adrenal glands, bladder, testes, ovaries, uterus, epididymis, seminal vesicle, heart, thymus, thyroid gland, trachea, esophagus, tongue, prostate, lungs, nasal cavity, kidneys, spleen, liver, pancreas, and brain were removed carefully, weighed, and fixed in a 10% formalin solution containing neutral phosphate-buffered saline. Thereafter, the organs were embedded in paraffin, stained with hematoxylin and eosin, and examined under light microscopy.

Determination of Tissue Silver

Tissues were digested with conc. nitric ac d by using a microwave digest on system (MARS 230/60, CEM). The concentration of silver in digested fluid was analyzed with a flameless method using an atomic absorption spectrophotometer equipped with a Zeeman graphite furnace (Perkin Elmer 5100ZL, Zeeman Furnace Module, USA) based on the NIOSH 7300 method [11]. The concentration of silver in the tissue was expressed as μg/g wet weight.

Statistical Analysis

Statistical analysis was performed with SPSS (Version 12). Statistical evaluation was performed by analysis of two-tailed Student's t-test or analysis of variance (ANOVA) following multiple comparison tests with Duncan's method. The level of statistical significance was set at $p < 0.05$

Results

Animal Observation, Food Consumption, and Effect on Body and Organ Weights

There were no significant differences in food consumption and water intake between treated male and female rats and the control group (data not shown). There were no significant dose-related changes in the body weight of female rats; however, there were significant ($P < 0.05$) dose-related decreases in the body weight of high-dose male rats at 4, 5, and 7 weeks of exposure at the conclusion of the study 13 weeks, and middle-dose male rats at 10 weeks of exposure (Figure 2). No significant organ-weight changes were observed in e ther the male or female rats after 90 days except for an increase ($P < 0.05$) in the weight of the left testis for the high-dose male rats, and for decreases ($P < 0.05$) in the weight of right k dney for the low-and middle-dose female rats (Tables 1 and 2).

Table 1. Relative organ weights for male rats after 90-day oral administration of silver nanoparticles (mean ± S.D., n≥9)

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Table 2. Relative organ weights for female rats after 90-day oral administration of silver nanoparticles (mean ± S.D., n≥9)

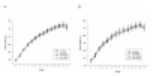


Figure 2. Body weight changes during 90-day oral administration of silver nanoparticles. A. Male. a Significant difference vs. control, p < 0.05. (10 weeks). b Significant difference vs. control, p < 0.05. (4, 5, 7~13 weeks). B. Female.

Effects on Clinical Chemistry and Hematology

There appeared to be increase ALP for male rats in the middle and high-dose groups statistically not significant (Table 3). However, there was a significant increase (P < 0.01) in alkaline phosphatase (ALP) for female rats in the high-dose groups (Table 4). A significant increase (P < 0.01) in cholesterol was also found in the middle and high-dose male rats and the high-dose female rats (Table 3 and 4). A significant increase (P < 0.05) in total bilirubin was noted in the m ddle-dose male rats (Table 3). A signif cant decrease in magnesium, protein, and inorganic phosphorus was found in the middle and high-dose female rats (Table 4). No significant changes in the hematological parameters were noted except for a significant increase (P < 0.05) in monocytes in the high-dose female rats (Table 5 and 6). The reticulocyte count for the low-dose female rats decreased signif cantly (p < 0.05) when compared with the control group (Table 7). Coagulation time in terms of the active partial thromboplastin time (APTT) and prothrombin time (PT) did not show any significant changes when compared with the control group (Figure 3).

Table 3. Serum values for male rats after 90-day oral administration of silver nanopart cles (mean ± S.D.)

Table 4. Serum values for female rats after 90-day oral administration of silver nanopart cles (mean ± S.D.)

Table 5. Hematological values for male rats after 90-day oral administration of silver nanoparticles (mean ± SD)

Table 6. Hematological values for female rats after 90-day oral administrat on of silver nanoparticles (mean ± SD).

Table 7. Reticulocyte counts for male and female rats after 90-day oral administration of silver nanoparticles (n = 5, EA/1000, mean ± SD)

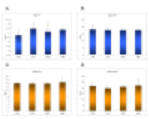


Figure 3. Coagulation times for male and female rats: A, male prothrombin time (PT); B, male active partial thromboplastine time (APPT); C, female PT; D, female APPT. (Error bars indicate standard deviation.)

Histopathologic Examination

In the liver, minimal bile-duct hyperplasia was identified in 4/10, 7/10, 8/10, and 6/10 of control, low, middle, and high-dose male rats, respectively (Table 8, Figure 4C). The higher incidence of bile-duct hyperplasia in treated male rats suggests a minimal effect due to silver nanoparticles in the treated groups. Minimal bile-duct hyperplasia was also present in 3/10, 7/10, 8/10, and 7/10 of the control, low, middle, and high-dose female rats, respectively (Table 9). Focal, multifocal, or lobular necrosis was noted in 0/10, 4/10, 5/10, and 4/10 of the control, low, middle, and high-dose male rats, respectively, and 0/10, 2/10, 2/10, and 2/10 of the control, low, middle, and high-dose female rats, respectively (Table 8 and 9, Figure 4B and 4D). The higher incidence of bile-duct hyperplasia, with or without necrosis, fibrosis, and/or pigmentat on, in the treated animals also suggests a treatment-related effect. Although there appeared to be a slight increase of minimal tubular basophilia in the kidneys of high-dose male rats, these changes were not statistically significant and thus not considered to be test article exposure related. Tubular basophilia were also more prevalent in the male rats compared to the female rats (Table 8). Minimum or mild renal unilateral or bilateral mineralization was observed in 5/10, 8/10, 7/10, and 9/10 of the control, low, middle, and high-dose female rats, respectively, indicating a treatment-related effect.

Table 8. Histopathological findings for male rats after 90-day oral administration of silver nanoparticles

Table 9. Histopathological findings for female rats after 90-day oral administration of silver nanoparticles

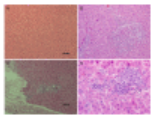


Figure 4. Histopathological findings in liver: (A) control liver, (B) multiple foci of inflammatory cell infiltrates, including eosinophils, especially around central vein and portal areas (C) bile duct hyperplasia, and (D) several foci of inflammatory cell infiltration, especially around central vein and sinusoid on hepatic lobules. Bar ind cates 100 μm. A. Control (×100). B. High dose (×100). C. High dose (×100). D. High dose (×200).

Histopathologic examination of lung tissue did not show any treatment-related effects.

In the intestines, pigmentation of villi was observed in 0/10, 0/10, 8/10, and 8/10 of the control, low, middle, and high-dose male rats, respectively (Table 8). This dose-dependent increase in the pigmentation of the villi indicated an apparent treatment-related effect (Figure 5). In contrast, there was a slight treatment-related increase in pigmentation of intestinal villi in female rats (Table 9).

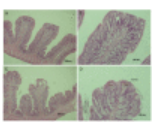


Figure 5. Histopathological findings in intestines of male rats dosed with 500 mg/kg silver nanoparticles for 90 days. A. Control male (×40). B. Control male (×100). C. High-dose male (×40). D. High-dose male (×100).

Silver Distribution in Tissues

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There was a statist cally significant ($P < 0.01$) dose-dependent increase in the silver concentration of all the tissue samples from the groups exposed to silver nanopart cles in this study (Table 10). In addition, a two-fold higher accumulation of silver in the kidneys of female rats when compared with the male rats occurred across all the dose groups indicating a marked gender-dependent distribution.

Table 10. Tissue silver content after 90-day oral administration of silver nanoparticles

Discussion

Silver nanoparticles are widely used as bacteric dal agents in consumer products, but their potential effects in humans remain poorly understood. Silver at doses below levels that cause argyria or argyriosis are generally considered to be relatively non-toxic [12]. Wijnhoven et al. have hypothesized that the toxic effects of silver are proportional to free silver ions, but it is unclear how this relates to silver nanoparticles. Absorption of silver after oral administration has been shown to be subject to a first-pass effect through the liver, resulting in excretion into the bile [13]. Uncleared silver has been shown to be deposited in the renal glomerular basement membrane [14-17], mesangium [18], Kupffer cells, and sinusoid endothelium cells in the liver [15].

Unlike the 28-day study of Kim et al. [9], the present study shows intestinal pigmentation and effects from exposure to silver nanoparticles. Dose-dependent increases in the silver concentrations in the intestinal villi, as observed in this and other reports [19], and in the blood, indicate that the orally absorbed silver from nanopart cles is able to enter the blood circulation and be distributed to other organs. Since similar effects have not been prev ously reported for soluble silver, there is a possibility that these effects are due to particles as opposed to ionized silver.

Increases in renal silver reported in the current study are consistent with literature showing that ionized silver is deposited in the renal glomerular basement membrane [14-17] and mesangium [18]. The gender-related distribution of silver nanoparticles in the kidneys was also consistent with the results from the 28-day [9], 90-day oral, and 90-day inhalat on studies [8]. The average nanoparticle sizes used in the 28-day and 90-day inhalation experiments were 15 nm and 18-19 nm, respectively, while the average nanopart cle size used in the 28-day and 90-day oral tox city studies was 60 nm and 56 nm, respectively. Common treatment-related endpoints and distribution were found in all these studies ind cating that distribution and toxicity do not appear to be dependent on particle size in the tested range or route of administration.

In previous reports, the target organs for silver nanoparticles were shown to be the liver in a 28-day oral toxicity study [9] and the liver and lungs in a 90-day inhalation study [8]. The results of the current study are consistent with previous reports with respect to the liver as the target organ and the tissue distribution of silver originating from nanoparticles. Liver toxicity as evaluated by histopathology included bile-duct hyperplasia and increased foci, which was consistent with the pathologic observations in the 28-day [9] oral toxicity and 90-day inhalation [8] toxicity studies. Increases in alkaline phosphatase and cholesterol were also consistent with the liver toxicity reported by Kim et al. and Sung et al.

In contrast to the 90-day inhalation study, no coagulation effects on peripheral blood were observed. Since there is similar hepatic pathology in the two studies, it is not clear whether increased coagulation times were due to hepatic injury in the inhalation study or some other mechanism.

Inhaled silver nanoparticles have been shown to cause lung inflammation [8]. These effects may be due to particle size since gold nanoparticles (which are not likely to be ionized) show similar effects [20]. Our very limited data makes it tempting to hypothesize that effects from silver nanoparticles are not only due to ionization of silver from the surface of silver nanoparticles, but may originate (at least in part) from direct effects of nanoparticles. The relationship between particle effect and effect from ionized silver could be tested by quantitatively examining target tissues for the presence of nanoparticles with a concurrent measurement of tissue ionized silver as opposed to measuring total tissue silver alone. If silver nanoparticles have part cle-related effects which are tissue specific and signif cant compared to effects from ionized silver, t will be important to incorporate such differences into future occupat onal and environmental risk assessments.

Conclusions

A LOAEL (lowest observable adverse effect level) of 125 mg/kg and a NOAEL (no observable adverse effect level) of 30 mg/kg are suggested from the current 90-day oral toxicity study. The LOAEL from this study is significantly lower than the LOAEL of 300 mg/kg derived from the 28-day oral toxicity study (Kim et al., 2008). However, the NOAEL derived from this study is consistent with the NOAEL of 30 mg/kg derived from the 28-day oral study (Kim et al., 2008).

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

IJY headed the study and performed pathologic analyses together with MYS, YHC, HKC, IHK and drafted the manuscript with YSK and BK. YSK headed all animal treatments with MYS, KSS, and HRR. JDP and JHL contributed to the distribution study. IJY, BK and KHO conceived and designed the study. All authors reviewed and interpreted data and read and approved the final manuscript.

Acknowledgements

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From: Murphey, Sheila A <Sheila.Murphey@fda.hhs.gov>
To: 'Cyshen@aol.com' <Cyshen@aol.com>
Cc: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: Question on Antibacteria Test (AATCC-100)
Date: Tue, May 29, 2012 9:43 am

Dear Chengyu Shen,

Thank you for your email. I must point out that I have not been consulted on your file and that I know nothing about its comments or about the comments from your initial review. I do not expect that situation to change. The only advice which I can provide to you is on the general principles of antimicrobial performance testing.

First, please note that FDA does not recognize any "standard test methods" for the performance of in vitro antimicrobial performance testing. The very wide variety of devices, proposed intended uses and antimicrobial agents seen by the agency very frequently requires that "standard" test methods be modified in order to best reflect the simulated conditions of use of the device being evaluated. The Agency does not object to modifications of test methods as long as they are scientifically sound and fully described.

The following principles should be observed in the design of your planned performance assays:
1. The test conditions should simulate, as closely as possible, the conditions of use of your device. For a wound dressing, this does mean avoiding excess fluid in the test environment
2. The device challenge inoculum should be measured at the time of device challenge.
3. An effective neutralizing agent must be used for enumeration of your assay results. This neutralizing agent should be clearly identified and you should submit the neutralization validation data with the rest of your test results.
4. Your assay should include challenge of the base device without the added antimicrobial agent as a control for non-specific material antimicrobial effects in your device
5. You should use a significant challenge inoculum for your assay; the Agency advises a concentration of at least 6 log10 CFU/mL. The volume in which you deliver this challenge can vary; however, you should measure your challenge inoculum in each assay that you perform.
6. You should identify and report the Limit of Quantitation (LOQ) of your assay - the limit below which your counts are no longer accurate; this is frequently 2 log10 CFU/mL and is why you need a significant inoculum in order to reliably detect a significant reduction in that inoculum
7. I do not advise any sponsor to seek performance claims by re-inoculating a specimen previously challenged with a microbial inoculum. This is particularly true beyond 72 hours, when microbial death due to nutrient deprivation can begin to occur.

If you wish to seek a claim for prolonged activity, the most straightforward way to test this is to use dressing specimens, including the needed controls, which have been maintained under simulated use (leach off) conditions for the number of days for which you seek a claim. After 6 or 7 days (whichever you prefer for your labeling claims) of simulated use exposure, transfer the specimens aseptically to a new sterile dish and perform the microbial challenge test as you would for unused product.

Be sure that whatever test methods you use in performance testing, they are clearly described in complete detail in your submission.

I hope that this information will be of use.

Regards,

Sheila A. Murphey, MD

Sheila A. Murphey, MD
Medical Officer, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
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Phone 301-796-6302 Fax 301-847-8109
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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Cyshen@aol.com [mailto:Cyshen@aol.com]
Sent: Tuesday, May 29, 2012 8:01 AM
To: Murphey, Sheila A
Subject: Question on Antibacteria Test (AATCC-100)

Dear Dr Murphy:

This is Chengyu Shen from Huizhou Foryou Medical Co., Ltd. We got your contact information from Dr Aprepalli. We are performing antibacterial testing on Silver Aginate Dressing per standard AATCC-100 as part of our effort to address deficiency letter for our 510(k) submission K120181. However, we have the following question, can you please kindly advise us?

The AATCC-100 requires inoculation 1 mL (10e6 population) of bacteria at day-1 and day-6 (since we are making 7 day claim) each for total of 2ml. However, our dressing is having difficulty to absorb 2 ml solution. In this case, can we use 0.5ml (day-1) + 0.5 ml (day-6), but doubled bacteria population (e.g. 2x10e6)?

Please kindly advise.

Chengyu Shen
Huizhou Foryou Medical Co., Ltd

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K141619/S003

FDA CDRH DMC
MAR 24 2015
Received

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S003, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent 2nd deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

You stated that your device has "an antibacterial effective time of three days." However, after close inspection of your protocol, it is clear that contact between your device and bacteria was technically only assessed for 24 hours, regardless of time point. With regards to conditioning of the device prior to inoculation, only 100 µL simulated wound fluid (SWF) was applied to the device every 24 hours. Because the volume is smaller than what would be needed to saturate the sample, it is not clear that the conditioning protocol leached the maximum amount of silver from the dressing sample, as might occur during use. We believe your experimental design should ideally measure the device's ability to inhibit bacterial growth on the dressing under continuous exposure to bacteria over your claimed time period. We therefore do not believe that this testing is sufficient to support a claim antibacterial preservative effectiveness for 3 days. Please consider one of the following options…….

Our Response:

We take the option 1, and revised test report is included. Test protocol has been reviewed by FDA before the test started.

1-CD
45

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary of new antibacterial test results:

Time point	Contact time	Bacteria (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero contact	Initial inoculum concentration (CFU/mL)	1.84×10^6	1.66×10^6	2.76×10^6	1.49×10^6	1.71×10^6	1.40×10^6
	Treated sample (CFU)	2.89×10^6	2.95×10^6	4.80×10^6	2.64×10^6	3.06×10^6	2.46×10^6
		2.70×10^6	2.40×10^6	4.54×10^6	2.45×10^6	3.09×10^6	2.41×10^6
		3.10×10^6	2.59×10^6	4.90×10^6	2.46×10^6	3.19×10^6	2.76×10^6
	Control sample (CFU)	3.35×10^6	2.98×10^6	5.28×10^6	2.76×10^6	2.95×10^6	2.59×10^6
		3.01×10^6	2.46×10^6	4.66×10^6	2.35×10^6	3.43×10^6	2.98×10^6
		3.09×10^6	2.86×10^6	4.89×10^6	2.55×10^6	3.09×10^6	2.50×10^6
72 hour contact	Treated sample (CFU)	<250	<250	<250	<250	<250	<250
		<250	<250	<250	<250	<250	<250
		<250	<250	<250	<250	<250	<250
	Control sample (CFU)	2.26×10^9	1.76×10^9	4.79×10^8	2.48×10^9	2.35×10^9	3.21×10^8
		1.85×10^9	3.79×10^9	3.76×10^8	0.88×10^9	2.21×10^9	4.45×10^8
		0.99×10^9	1.20×10^9	5.71×10^8	3.58×10^9	4.44×10^9	6.16×10^8
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
	Average Log reduction	4.064	4.025	4.278	4.003	4.095	4.008
	Control plate	no colony	no colony	no colony	no colony	no colony	no colony

Challenge organisms

Test Organism	Stain
Enterococcus faecalis	ATCC 29212
Escherichia coli	ATCC 8739
Klebsiella pneumoniae	ATCC 4352
Pseudomonsa aeruginosa	ATCC 9027
Staphylococcus aureus	ATCC 6538
Streptococcus pyogenes	ATCC 19615

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

FDA Comment 2:

If you choose to conduct additional testing (per Deficiency 1a, 1b above):
Your test protocol appears to indicate that, following the addition of the neutralization broth, that bacteria are combined with the hot nutrient agar before it cools and solidifies. This method could lyse, inactivate, and/or hinder bacterial growth depending on temperature and distort your test results. Instead, please first prepare the nutrient agar plates and let them cool/solidify without adding bacteria. Prior to using these plates, place a control plate in the incubator for 24 hours to make sure that no contamination of other bacteria will grow. After performing your serial dilution on your samples, plate each dilution evenly on the surface of your nutrient agar plates using a plate spreader.

Our Response:

We have adapted the FDA suggested methodology in our new test.

FDA Comment 3:

In your January 10, 2015 response, you stated that you revised your labeling to address Deficiency 8e of our September 19, 2014 letter. However, your submitted labeling did not reflect those revisions. Per Deficiency 8e, please remove the sentence "The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment" from your labeling (Section 13, p. 3).

Our Response:

Corrected

FDA Comment 4:

You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

Our Response:

The packaging integrity was tested over the two year real-time aging period. These reports were in our January 10, 2015 response, with the reports names below:

014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

These reports are included again this time for your convenience.

FDA Comment 5:

Your labeling contains symbols that are not accompanied by explanatory text. Please note 21 CFR 801.15(c)(1), which states that "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language." Thus, please revise your labeling such that all symbols are accompanied by explanatory text.

Our Response:

Corrected in Section 13

List of Documents included in this supplemental submission (S003):

001_Response to K141619 2nd Deficiency
002_New Antibacterial Testing Report
003_Section 13_Labeling RE3
004_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
005_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
006_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen Charles Shen

Charles Shen, Official Correspondent
Date: March 20, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S003, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent 2nd deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

You stated that your device has "an antibacterial effective time of three days." However, after close inspection of your protocol, it is clear that contact between your device and bacteria was technically only assessed for 24 hours, regardless of time point. With regards to conditioning of the device prior to inoculation, only 100 µL simulated wound fluid (SWF) was applied to the device every 24 hours. Because the volume is smaller than what would be needed to saturate the sample, it is not clear that the conditioning protocol leached the maximum amount of silver from the dressing sample, as might occur during use. We believe your experimental design should ideally measure the device's ability to inhibit bacterial growth on the dressing under continuous exposure to bacteria over your claimed time period. We therefore do not believe that this testing is sufficient to support a claim antibacterial preservative effectiveness for 3 days. Please consider one of the following options…….

Our Response:

We take the option 1, and revised test report is included. Test protocol has been reviewed by FDA before the test started.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Summary of new antibacterial test results:

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Our Response:

We have adapted the FDA suggested methodology in our new test.

FDA Comment 3:

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Our Response:

Corrected

FDA Comment 4:

You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

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Our Response:

Corrected in Section 13

List of Documents included in this supplemental submission (S003):

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We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen

Charles Shen, Official Correspondent
Date: March 20, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Section 13: Proposed Labeling

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

Rx Only
Version: A/0

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure containing silver particles which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. The total maximum amount of silver partilces is 4ug/cm^3. The silver is present as a preservative to inhibit bacterial colonization within the dressing. LUOFUCON® Silver Foam Dressing has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.
The **Silver Foam Dressing with PU Backing** consists of silver foam and breathable polyurethane film for waterproof. The **Bordered Silver Foam Dressing** is silver foam on a PU/PET film or non-woven coated with acrylic adhesive and extends to act as a border adhesive to allow fixation without secondary dressing or fixation bandage.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers(venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns(1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

In Vitro Study Results:
This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria:

Proven Antibacterial Effectiveness	
Bacterial	72 Hour Log Reduction
Staphylococcus aureus (ATCC 6538)	4 Log
Streptococcus pyogenes (ATCC 19615)	4 Log
Enterococcus faecalis (ATCC 29212)	4 Log
Escherlchia coli (ATCC 8739)	4 Log
Klesiella pneumonlae (ATCC 4352)	4 Log
Pseudomonas aeruginosa (ATCC 9027)	4 Log

Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. The dressing should be left on the skin for no more than three days.

Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Specifications (Including 3mm and 5mm)

Foam or With PU Backing	PU or Non-woven Adhesive
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
125×100	150×150(100×100)
150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.2 Pouch Label

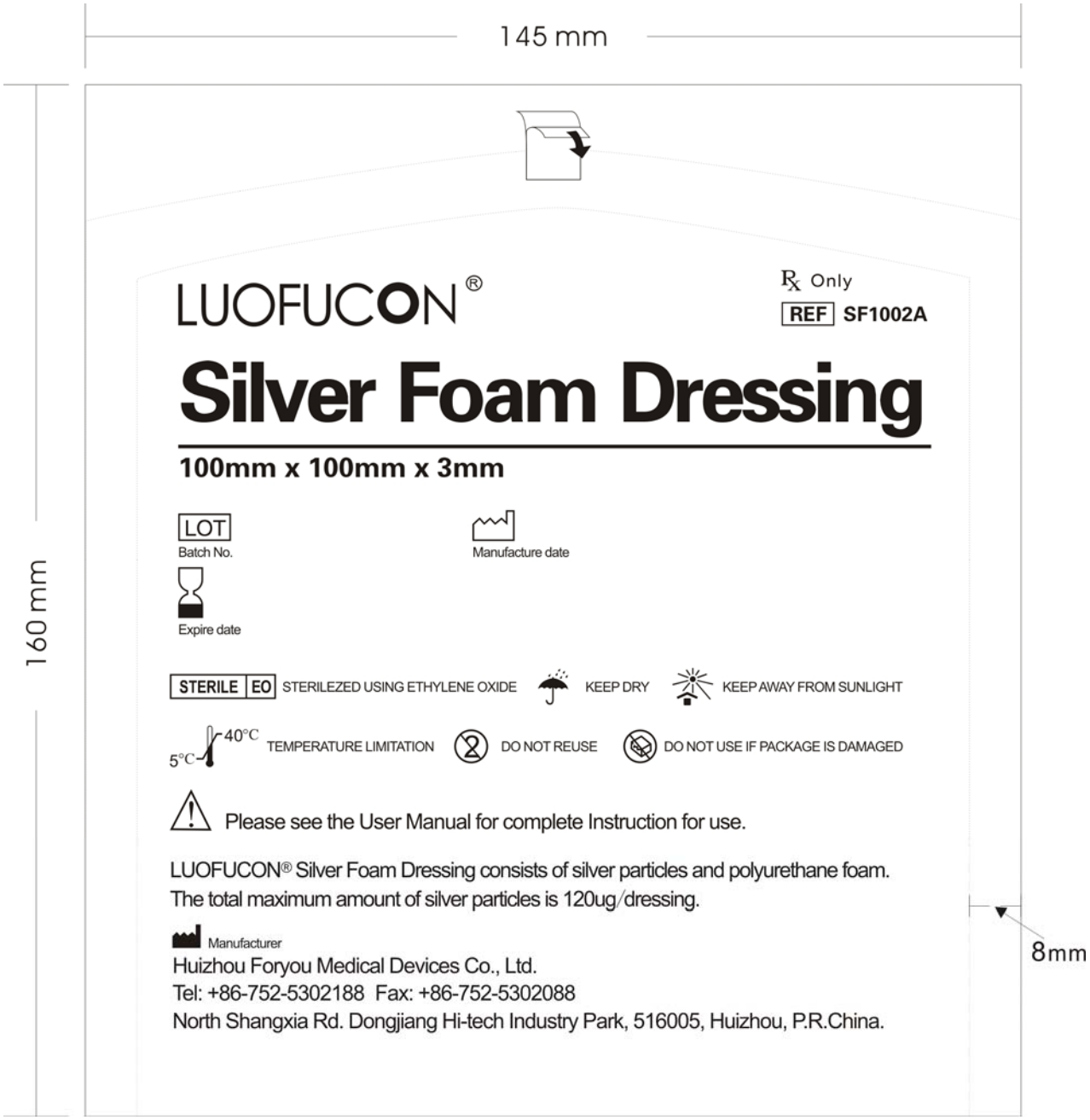
Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 13: Labeling: Prescription

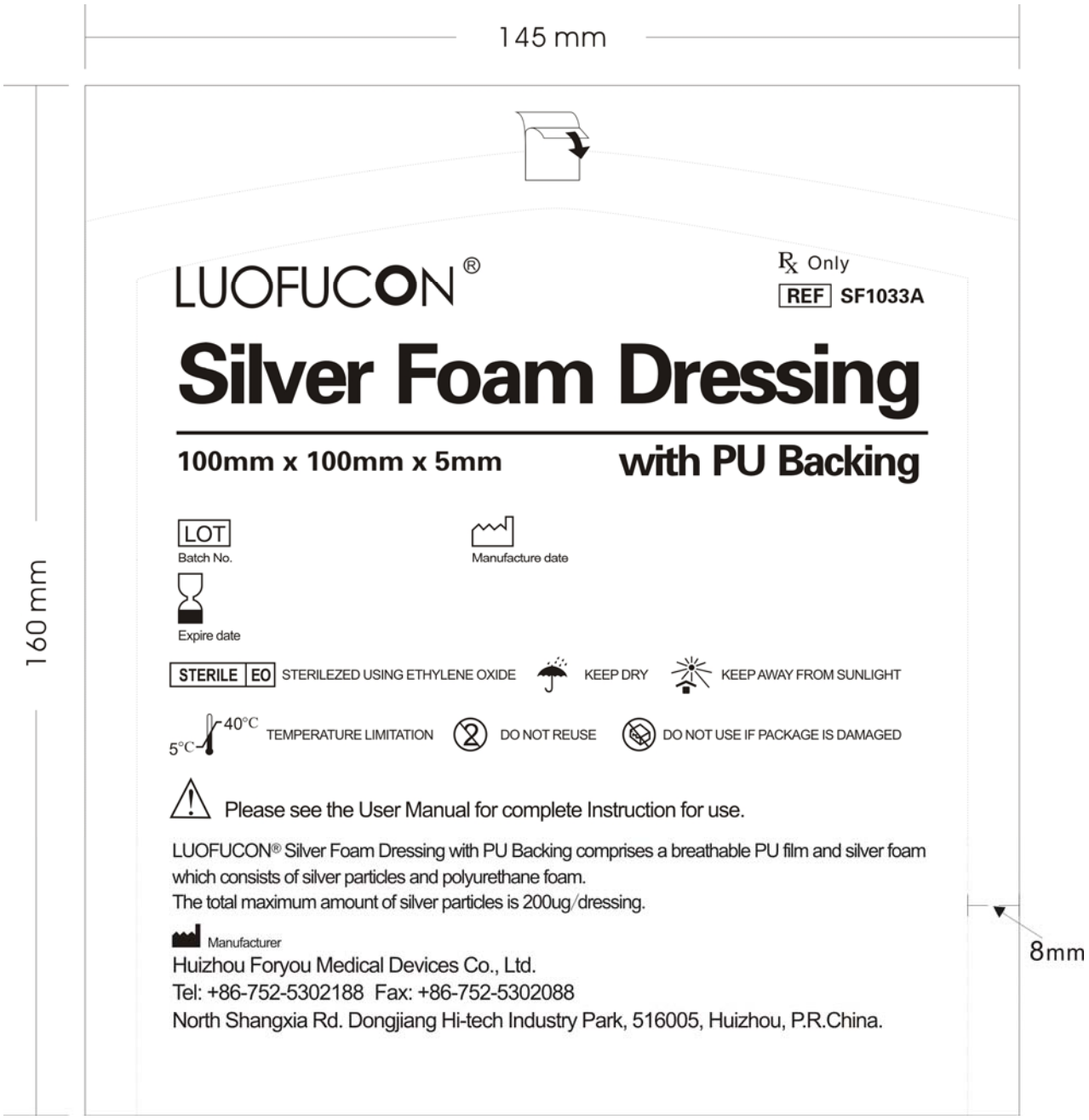
Variant 1:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

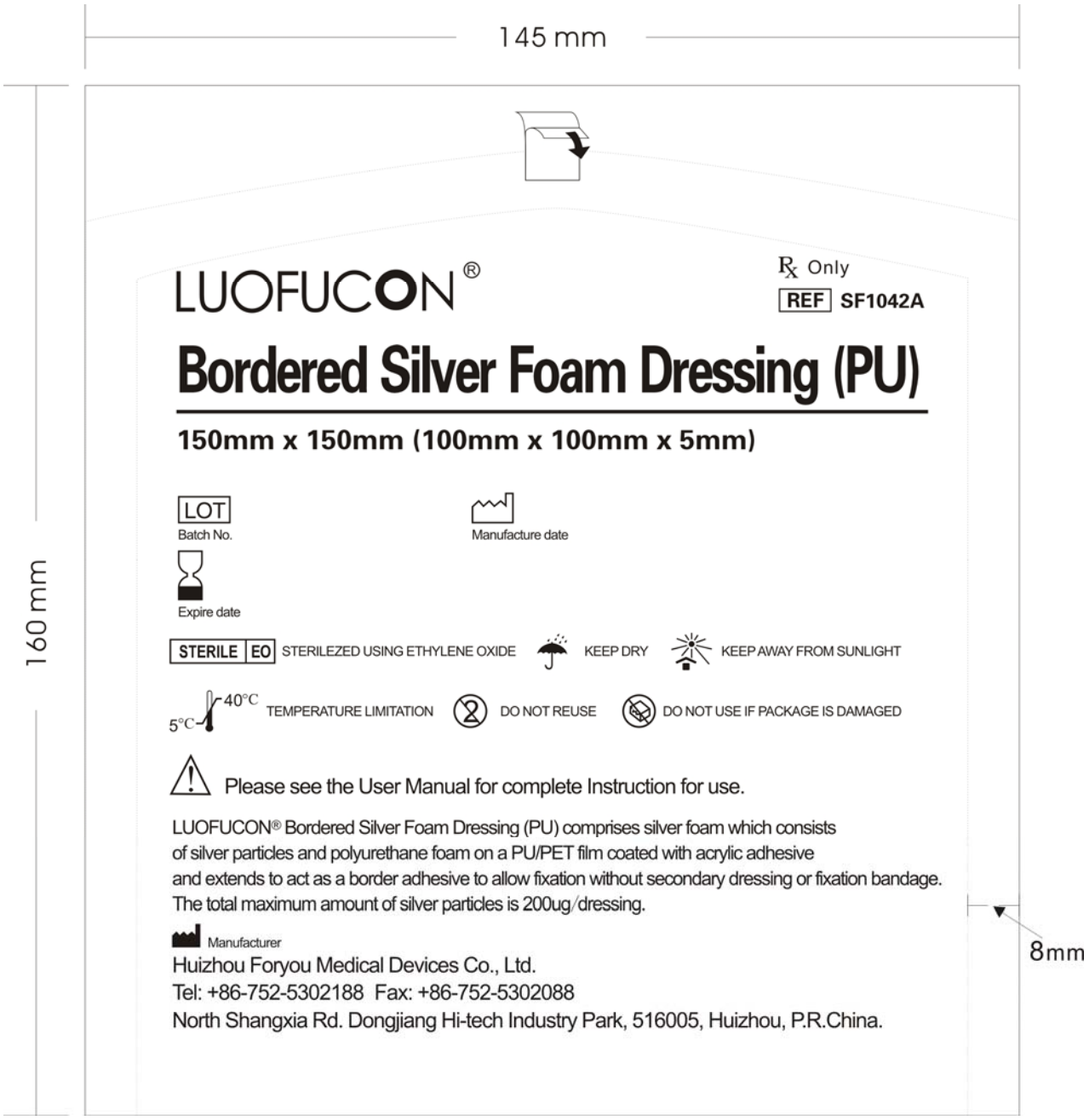
Variant 2:



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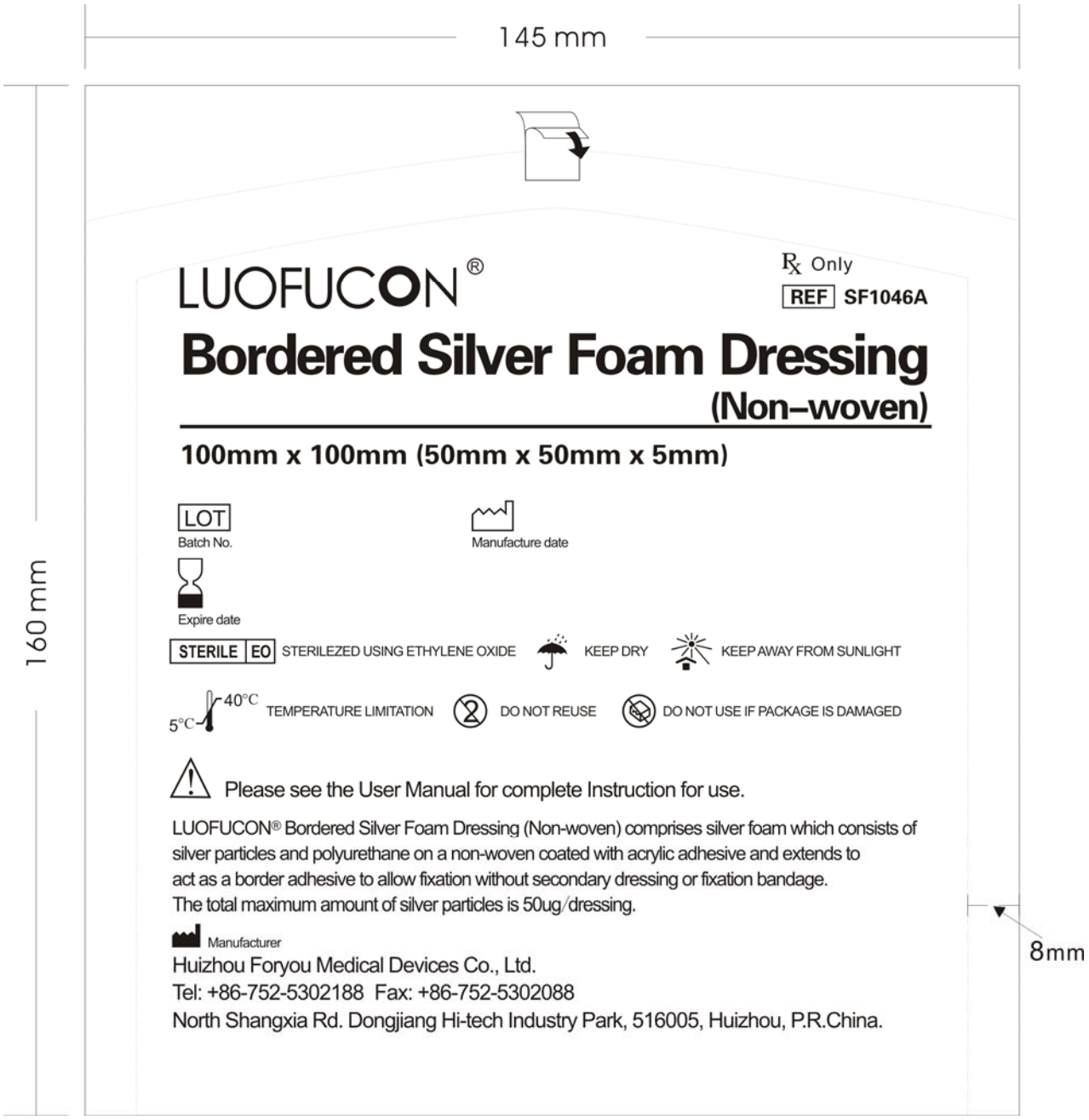
Variant 3:



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Variant 4:



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13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 1



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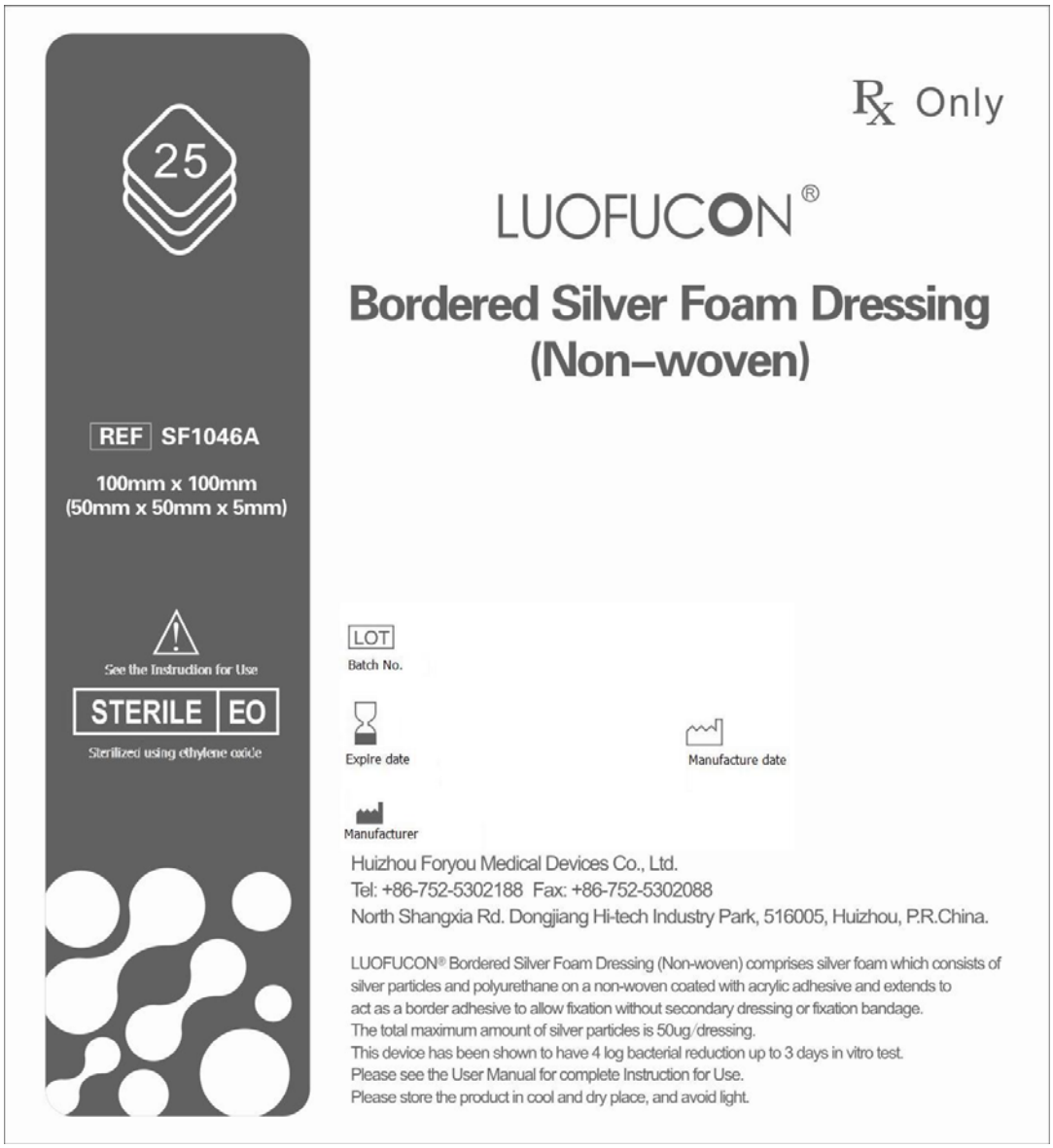
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(b)(4) Test Data

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

Huizhou Foryou Medical Devices Company, Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester Lane, Unit-B
Pennington, New Jersey 08534

Re: K141619
Trade/Device Name: Luofucon Silver Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 20, 2015
Received: March 24, 2015

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		X		X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Please clarify whether there are any prior submissions that are relevant to this device. If not, please state that there were no prior submissions.				
B. Device Description				
10)				

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.		X		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Please describe the function of the non-woven material layer in the fourth variant of your device.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		X		X
Comments? Please describe the thicknesses of the secondary layers in the second, third, and fourth variants of your device.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				

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a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? The provided package labeling in p. 7 of Section 13 is too small to read and is thus illegible; please provide a zoomed-in depiction of the labeling.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	

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25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		X
Comments? Please identify the complete materials of construction for each of the variants of your device, including secondary layers and any adhesives that are used.				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

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31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

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Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.07.01 11:49:37 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.07.01 16:12:19 -04'00'
Division Sign-Off (digital signature optional)*	David Krause -S 2014.07.01 16:18:50 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		X		X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Please clarify whether there are any prior submissions that are relevant to this device. If not, please state that there were no prior submissions.				
B. Device Description				
10)				

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.		X		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Please describe the function of the non-woven material layer in the fourth variant of your device.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		X		X
Comments? Please describe the thicknesses of the secondary layers in the second, third, and fourth variants of your device.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				

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a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? The provided package labeling in p. 7 of Section 13 is too small to read and is thus illegible; please provide a zoomed-in depiction of the labeling.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	

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25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
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F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
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Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		X
Comments? Please identify the complete materials of construction for each of the variants of your device, including secondary layers and any adhesives that are used.				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

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36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.07.01 11:49:37 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.07.01 16:12:19 -04'00'
Division Sign-Off (digital signature optional)*	David Krause -S 2014.07.01 16:18:50 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
B. Device Description				
10)				

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments?				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(21 CFR 807.87 unless otherwise indicated)

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16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments?				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)

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b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)

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Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
× does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
× does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	×			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			×	
38) If literature is referenced in the submission, submission includes:			×	
39) For each completed nonclinical (i.e., animal) study conducted			×	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
× is not an in vitro diagnostic device.				

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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.08.05 16:12:59 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.08.06 14:58:04 -04'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Food and Drug Administration

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Expiration Date: January 31, 2017
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510(k) Number *(if known)*
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- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cortez, Karoll
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Date: Wednesday, August 13, 2014 1:40:54 PM
Importance: High

Dear Peter,
Hi, How are you?
I am an infectious disease doc , I do infection control consults.
However, I still need you give me a question to go by. What are your questions or instructions for me? Could you please articulate them?
Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=435&E=&S=E

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: CDRH Center Tracking System
To: Yang, Peter (CDRH)
Subject: CTS Assignment Notification: K141619 has been assigned to you
Date: Wednesday, June 18, 2014 12:59:39 PM

June 18, 2014

This document has been assigned to you in the Center Tracking System (CTS).

Document # :	K141619
Document Type :	510(k)
Workflow State :	Requires Recommendation
Assignor :	Jiyoung Dang [JMD]

You may visit the Center Tracking System (CTS) at: http://cts.fda.gov/division-tracking for more information.

Please contact Jiyoung Dang [JMD] at jiyoung.dang@fda.hhs.gov or at 301-796-6437 if you have any questions or comments.

This is an automated e-mail. Please do not reply to this message.

If you would like NOT to receive these messages in the future, please uncheck 'Receive Assignment Email Notification' checkbox in the User Preferences section of your CTS user profile, accessible through the toolbar in CTS.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: CDRH Center Tracking System
To: Yang, Peter (CDRH)
Subject: CTS Assignment Notification: K141619/S001 has been assigned to you
Date: Wednesday, August 06, 2014 4:53:57 PM

August 6, 2014

This document has been assigned to you in the Center Tracking System (CTS).

Document # :	K141619/S001
Document Type :	510(k)
Workflow State :	Requires Recommendation
Assignor :	David Krause [DXK]

You may visit the Center Tracking System (CTS) at: http://cts.fda.gov/division-tracking for more information.

Please contact David Krause [DXK] at david.krause@fda.hhs.gov or at 301-796-6442 if you have any questions or comments.

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: CDRH Center Tracking System
To: Yang, Peter (CDRH)
Subject: CTS Assignment Notification: K141619/S001 has been assigned to you
Date: Friday, July 25, 2014 11:14:43 AM

July 25, 2014

This document has been assigned to you in the Center Tracking System (CTS).

Document # :	K141619/S001
Document Type :	510(k)
Workflow State :	Requires Recommendation
Assignor :	Jiyoung Dang [JMD]

You may visit the Center Tracking System (CTS) at: http://cts.fda.gov/division-tracking for more information.

Please contact Jiyoung Dang [JMD] at jiyoung.dang@fda.hhs.gov or at 301-796-6437 if you have any questions or comments.

This is an automated e-mail. Please do not reply to this message.

If you would like NOT to receive these messages in the future, please uncheck 'Receive Assignment Email Notification' checkbox in the User Preferences section of your CTS user profile, accessible through the toolbar in CTS.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Dang, Jiyoung M
To: Ashar, Binita S; Krause, David
Cc: Yang, Peter (CDRH)
Subject: DUE TOMORROW - K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 01, 2014 4:16:03 PM

K141619
Rta recommendation – RTA1
Rta due – TOMORROW (7/2)
Checklist on docman

DocMan: http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Dang, Jiyoung M
To: Krause, David
Cc: Yang, Peter (CDRH)
Subject: DUE TOMORROW - ready for division review/concurrence - K141619/S001 - RTAA
Date: Wednesday, August 06, 2014 2:59:50 PM

DUE TOMORROW

K141619/S001
Rta recommendation – RTAA
Checklist on docman

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: no-reply@fda.gov
To: Yang, Peter (CDRH)
Subject: FDA Submission Lead Reviewer Assigned - DocMan
Date: Wednesday, July 23, 2014 12:10:44 PM

****This is a system generated email notification from DocMan****

You have been assigned **LEAD REVIEWER** of a parent document. The details are as follows:

Submission Number	K141619
Applicant	Huizhou Foryou Medical Devices Co, Ltd
Trade Name	Luofucon silver foam dressing
Interactive Email Address	K141619@docs.fda.gov

To access the document in DocMan, please click on the submission number above. For further assistance, please access the DocMan Reference Guide or other available reference material provided by CDRH Staff.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: no-reply@fda.gov
To: Yang, Peter (CDRH)
Subject: FDA Submission Lead Reviewer Assigned - DocMan
Date: Friday, July 25, 2014 11:14:59 AM

****This is a system generated email notification from DocMan****

You have been assigned **LEAD REVIEWER** of a parent document. The details are as follows:

Submission Number	K141619
Applicant	Huizhou Foryou Medical Devices Co, Ltd
Trade Name	Luofucon silver foam dressing
Interactive Email Address	K141619@docs.fda.gov

To access the document in DocMan, please click on the submission number above. For further assistance, please access the DocMan Reference Guide or other available reference material provided by CDRH Staff.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: no-reply@fda.gov
To: Yang, Peter (CDRH)
Subject: FDA Submission Lead Reviewer Assigned - DocMan
Date: Wednesday, June 18, 2014 12:59:47 PM

****This is a system generated email notification from DocMan****

You have been assigned **LEAD REVIEWER** of a parent document. The details are as follows:

Submission Number	K141619
Applicant	Huizhou Foryou Medical Devices Co, Ltd
Trade Name	Luofucon silver foam dressing
Interactive Email Address	K141619@docs.fda.gov

To access the document in DocMan, please click on the submission number above. For further assistance, please access the DocMan Reference Guide or other available reference material provided by CDRH Staff.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: no-reply@fda.gov
To: Yang, Peter (CDRH)
Subject: FDA Submission Lead Reviewer Unassigned - DocMan
Date: Friday, July 25, 2014 11:14:54 AM

****This is a system generated email notification from DocMan****

The Lead Reviewer for K141619 has been re-assigned by System. You are no longer the Lead Reviewer of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: no-reply@fda.gov
To: Yang, Peter (CDRH)
Subject: FDA Submission Lead Reviewer Unassigned - DocMan
Date: Wednesday, July 23, 2014 12:10:39 PM

****This is a system generated email notification from DocMan****

The Lead Reviewer for K141619 has been re-assigned by System. You are no longer the Lead Reviewer of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From:	Cortez, Karoll
To:	Claverie, Elizabeth F
Cc:	Yang, Peter (CDRH)
Subject:	FW: K141619 Peter"s consult
Date:	Thursday, September 18, 2014 10:32:13 PM
Attachments:	consult memo K1415476. Sept 18 2014.final2.pdf consult memo K1415476. Sept 18 2014.final2.doc
Importance:	High

Liz, this is the consult for your signature.
Peter, you already have this memo in word, but here it is again for both of your convenience.
Thank you so much for your patience.
Good night
Karoll

From: Cortez, Karoll
Sent: Thursday, September 18, 2014 3:40 PM
To: Claverie, Elizabeth F
Subject: K141619 Peter's consult

For your signature
Thanks so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Liu, Lixin
Subject: FW: K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 22, 2014 5:07:00 PM
Attachments: K141863 RTAChecklist RTA1.pdf

Lixin,

This is a sample email of what I send to Jiyoung with an RTA1 decision.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Yang, Peter (CDRH)
Sent: Monday, June 30, 2014 2:44 PM
To: Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Subject: K141619 RTA checklist completed [RTA1]

Hi Jiyoung,

I've completed the RTA checklist for K141619 – Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. The submission lacks several elements, hence RTA1. Today, Monday, is FDA Day **13**.

Please let me know if you have any comments or questions. The checklist can be found on DocMan:

http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Email: peter.yang@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cortez, Karoll
To: Yang, Peter (CDRH)
Subject: FW: K141619 urgent for Peter Yang
Date: Wednesday, September 17, 2014 2:13:32 PM
Attachments: consult memo K1415476.Sept 17 2014.final.doc
Importance: High

For your eyes only

From: Cortez, Karoll
Sent: Wednesday, September 17, 2014 1:57 PM
To: Claverie, Elizabeth F
Subject: K141619 urgent for Peter Yang
Importance: High

Liz,
Please see the memo.
I am not sure if this is in 4 part harmony. I did try though
Thanks
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "official-K141619@docs.fda.gov"
Subject: FW: K141619 was Refused
Date: Wednesday, July 09, 2014 11:22:00 AM
Attachments: K141619.RTAChecklist.RTA1.pdf

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Peter Yang [mailto:peter.yang@fda.hhs.gov]
Sent: Tuesday, July 01, 2014 4:20 PM
To: CYSHEN@AOL.COM
Cc: Yang, Peter (CDRH)
Subject: K141619 was Refused

July 1, 2014

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K141619. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K141619, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf
.

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Dear Mr. Shen,

Thank you for your March 20, 2015 response to our February 2, 2015 letter. We are currently in the interactive review process and have but a few days to complete review; as such, we request your response to the following deficiencies via email by tomorrow, Wednesday, April 1, 2015 at 12 pm Eastern.

1. Please revise your indications for use in your labeling, 510(k) Summary, and Indications for Use statement to remove the statement regarding silver serving as a preservative. We request this to facilitate comparison of the IFU with the predicate device and to limit the indications for use to the conditions that your device will treat. Other language discussing silver in your User Manual and 510(k) Summary (given the revisions requested below) remain appropriate.
2. In your User Manual labeling, please revise "Proven Antibacterial Effectiveness" to "Proven Antibacterial Preservative Effectiveness." We request this change to clarify that the role of silver is to act as a preservative.
3. Please revise your 510(k) Summary as follows:
    * Please remove Section numbers and references to other areas of your submission. The 510(k) Summary is a standalone document.
    * Please update the Summary Date.
    * Please move the "Silver serves as a preservative..." statement from the Indications for Use statement to the Product Information section above it. This is so that your product information can be placed in the proper context of silver as a preservative.
    * Please correct typos in the Predicate Indications for Use in Table 5.1.
    * When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
    * Your statements regarding AATCC 100 imply that testing was done above and beyond what was required to establish substantial equivalence. Additionally, the term "99.99%" does not accurately reflect your testing. Please revise the paragraph discussing AATCC-100 to state "To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in in vitro testing."
    * The next paragraph following discussion of AATCC 100 references promotional material as discussed above. The statement in this paragraph regarding dressing changes is not accurate, as the dressing should be changed at least every three days, and because the device is not be used "for antibacterial purpose." Thus, please remove this paragraph, which begins "The 510(k) Summary of the predicate device lists effective duration of 5-7 days..." from your 510(k) Summary.

Please respond to these deficiencies by providing a revised Indications for Use statement, 510(k) Summary, and User Manual via email by tomorrow,

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Wednesday, April 1, 2015, at 12 pm Eastern. If you have any questions, please email as needed.

Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: cyshen@aol.com
Cc: K141619@docs.fda.gov
Subject: K141619 - interactive review
Date: Tuesday, March 31, 2015 11:31:00 AM

Dear Mr. Shen,

Thank you for your March 20, 2015 response to our February 2, 2015 letter. We are currently in the interactive review process and have but a few days to complete review; as such, we request your response to the following deficiencies via email by tomorrow, Wednesday, April 1, 2015 at 12 pm Eastern.

1. Please revise your indications for use in your labeling, 510(k) Summary, and Indications for Use statement to remove the statement regarding silver serving as a preservative. We request this to facilitate comparison of the IFU with the predicate device and to limit the indications for use to the conditions that your device will treat. Other language discussing silver in your User Manual and 510(k) Summary (given the revisions requested below) remain appropriate.
2. In your User Manual labeling, please revise "Proven Antibacterial Effectiveness" to "Proven Antibacterial Preservative Effectiveness." We request this change to clarify that the role of silver is to act as a preservative.
3. Please revise your 510(k) Summary as follows:
    a. Please remove Section numbers and references to other areas of your submission. The 510(k) Summary is a standalone document.
    b. Please update the Summary Date.
    c. Please move the "Silver serves as a preservative…" statement from the Indications for Use statement to the Product Information section above it. This is so that your product information can be placed in the proper context of silver as a preservative.
    d. Please correct typos in the Predicate Indications for Use in Table 5.1.
    e. When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
    f. Your statements regarding AATCC 100 imply that testing was done above and beyond what was required to establish substantial equivalence. Additionally, the term "99.99%" does not accurately reflect your testing. Please revise the paragraph discussing AATCC-100 to state "To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing."
    g. The next paragraph following discussion of AATCC 100 references promotional material as discussed above. The statement in this paragraph regarding dressing changes is not accurate, as the dressing <u>should</u> be changed at least every three days, and because the device is not be used "for antibacterial purpose." Thus, please remove this paragraph, which begins "The 510(k) Summary of the predicate device lists effective duration of 5-

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 days…" from your 510(k) Summary.

Please respond to these deficiencies by providing a revised Indications for Use statement, 510(k) Summary, and User Manual via email by tomorrow, Wednesday, April 1, 2015, at 12 pm Eastern. If you have any questions, please email as needed.

Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Yang, Peter (CDRH)
To: Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Subject: K141619 RTA checklist completed [RTA1]
Date: Monday, June 30, 2014 2:43:00 PM

Hi Jiyoung,

I've completed the RTA checklist for K141619 – Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. The submission lacks several elements, hence RTA1. Today, Monday, is FDA Day **13**.

Please let me know if you have any comments or questions. The checklist can be found on DocMan:

http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
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From: Yang, Peter (CDRH)
To: Chang, Cynthia (Cynthia.Chang@fda.hhs.gov)
Subject: K141619 RTA checklist
Date: Friday, June 27, 2014 5:26:00 PM
Attachments: K141619.RTAChecklist.RTA1.pdf

Hi Cynthia,

Here's the RTA checklist for K141619, Huizhou Foryou Medical Devices Silver Foam Dressing. I recommend RTA1. Let me know what you think.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From:	Peter Yang
To:	CYSHEN@AOL.COM
Cc:	Yang, Peter (CDRH)
Subject:	K141619 was Refused
Date:	Tuesday, July 01, 2014 4:26:42 PM
Attachments:	K141619.RTAChecklist RTA1.pdf

July 1, 2014

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K141619. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K141619, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf .

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cortez, Karoll
To: Yang, Peter (CDRH)
Subject: K141619
Date: Thursday, September 18, 2014 3:43:54 PM
Attachments: consult memo K1415476. Sept 18 2014.final2.doc

Use this one
Have good night

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Silver serves as a preservative against bacterial growth in the dressing material

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial preservative agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	5-7 days

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device description:

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

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Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Silver serves as a preservative against bacterial growth in the dressing material

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
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Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

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Description	Our Device	Predicate Device 1 (K110062)
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Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial preservative agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

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Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	5-7 days

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

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Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Food and Drug Administration
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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From: Cortez, Karoll
To: Yang, Peter (CDRH)
Subject: K141619
Date: Thursday, September 18, 2014 3:42:12 PM
Attachments: consult memo K1415476. Sept 18 2014.final2.pdf

Peter,

Here is the 4 part harmony consult Liz has concurred with this as we worked until now to get it into the correct format.

She will stamp her digital signature later tonight.

But here you have it. Please keep it confidential.

Thanks you SO MUCH. You are very gentle and understanding.

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K141619/S001
Huizhou Foryou Medical Devices, Co., Ltd.
Trade Name: LUOFUCON Silver Foam Dressing

We have reviewed your Section 510(k) premarket notification of intent to market your device (K141619). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

1. With regards to your intended use:

    a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

    b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary.

2. You have provided a predicate device which also contains silver. In your submission, you state that your device has "relatively low silver release" "compared to other products in the market." However, you have not compared the differences, if any, in silver content between your device and your predicate device. If there is a difference in silver content, this may represent a meaningful difference in the technological characteristics of your device. Please discuss any differences in silver content and, if differences exist, please provide a justification for the increase in silver content. This justification may be in the form of a predicate device which contains the same or greater silver content in the same form (i.e., metallic silver). Please also include an assessment of the toxicological risk of silver in your device, including the potential for toxicity given the potential maximum dose, NOAEL, LOAEL, LD50, etc.

3. You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to

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understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.

b. We suggest providing, for each reagent, known published toxicological information.

c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits.

4. You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount

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of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

5. With regards to your antibacterial activity testing:

   a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

   b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

   c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

   d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

   e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

   f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

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g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

6. With regard to your shelf life:

   a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

   b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

7. You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

8. With regards to your labeling:

   a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

   b. Per the discussion above regarding the role of silver, we believe it is important to emphasize that silver is present only as a preservative for the dressing. Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

   c. You state in your User Manual that the device maintains a moist environment "to accelerate healing process." This statement implies that the dressing actively promotes wound healing, which we believe to be a new intended use of this device. We would therefore require that this statement be substantiated by clinical data as part of a PMA submission for a Class III device. Accordingly, please remove this statement.

   d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However,

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you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

e. You present an "In vitro Study Results" section in your package labeling that details the biocompatibility and antibacterial effectiveness testing that has been performed on your device. In addition, your Instructions for Use contains an "Adverse Reactions" section that similarly discusses your biocompatibility testing. However, we believe this text implies that additional performance testing has been conducted beyond biocompatibility and performance testing needed for 510(k) clearance when such testing has not been performed. Therefore, please remove this section.

f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.

g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."

h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.

i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

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K141619/S001
Huizhou Foryou Medical Devices, Co., Ltd.
Trade Name: LUOFUCON Silver Foam Dressing

We have reviewed your Section 510(k) premarket notification of intent to market your device (K141619). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

1. With regards to your intended use:

    a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

    b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary.

2. You have provided a predicate device which also contains silver. In your submission, you state that your device has "relatively low silver release" "compared to other products in the market." However, you have not compared the differences, if any, in silver content between your device and your predicate device. If there is a difference in silver content, this may represent a meaningful difference in the technological characteristics of your device. Please discuss any differences in silver content and, if differences exist, please provide a justification for the increase in silver content. This justification may be in the form of a predicate device which contains the same or greater silver content in the same form (i.e., metallic silver). Please also include an assessment of the toxicological risk of silver in your device, including the potential for toxicity given the potential maximum dose, NOAEL, LOAEL, LD50, etc.

3. You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to

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understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.

b. We suggest providing, for each reagent, known published toxicological information.

c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits.

4. You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount

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of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

5. With regards to your antibacterial activity testing:

   a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

   b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

   c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

   d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

   e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

   f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

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g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

6. With regard to your shelf life:

   a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

   b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

7. You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

8. With regards to your labeling:

   a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

   b. Per the discussion above regarding the role of silver, we believe it is important to emphasize that silver is present only as a preservative for the dressing. Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

   c. You state in your User Manual that the device maintains a moist environment "to accelerate healing process." This statement implies that the dressing actively promotes wound healing, which we believe to be a new intended use of this device. We would therefore require that this statement be substantiated by clinical data as part of a PMA submission for a Class III device. Accordingly, please remove this statement.

   d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However,

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you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

e. You present an "In vitro Study Results" section in your package labeling that details the biocompatibility and antibacterial effectiveness testing that has been performed on your device. In addition, your Instructions for Use contains an "Adverse Reactions" section that similarly discusses your biocompatibility testing. However, we believe this text implies that additional performance testing has been conducted beyond biocompatibility and performance testing needed for 510(k) clearance when such testing has not been performed. Therefore, please remove this section.

f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.

g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."

h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.

i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

K141619/S002
Huizhou Foryou Medical Devices, Co., Ltd.
Trade Name: LUOFUCON Silver Foam Dressing

Dear Mr. Shen:

Thank you for your January 10, 2015 response to our September 19, 2014 letter requesting additional information. In reviewing this response, we identified several additional issues related to your antibacterial effectiveness testing. Our current policy is to try and resolve all remaining issues following issue of one letter requesting additional information in an interactive manner without placing the file on hold for a second time. However, because we did not initially communicate these issues to you in our September 19, 2014 letter, we are placing your file on a second hold to give you additional time to address these issues. To complete the review of your submission, please address the following deficiencies:

1. You stated that your device has "an antibacterial effective time of three days." However, after close inspection of your protocol, it is clear that contact between your device and bacteria was technically only assessed for 24 hours, regardless of time point. With regards to conditioning of the device prior to inoculation, only 100 µL simulated wound fluid (SWF) was applied to the device every 24 hours. Because the volume is smaller than what would be needed to saturate the sample, it is not clear that the conditioning protocol leached the maximum amount of silver from the dressing sample, as might occur during use. We believe your experimental design should ideally measure the device's ability to inhibit bacterial growth on the dressing under continuous exposure to bacteria over your claimed time period. We therefore do not believe that this testing is sufficient to support a claim antibacterial preservative effectiveness for 3 days. Please consider one of the following options:

    a. Please conduct additional testing with device samples and negative controls, inoculating all samples at time t=0 instead of at your specified time points and adding SWF as before. This will ensure that your preservative effectiveness testing adequately demonstrates resistance to bacterial colonization over 3 days, rather than 24 hours. We believe such an experimental design better emulates the clinically relevant scenario where your dressing remains on a wound for up to 3 days.

    b. Please conduct additional testing with device samples and controls with maximum leaching of silver over 3 days. In your January 10, 2015 response, you provided the results of silver leachability testing using samples that were saturated with SWF. Repeatedly saturating test samples with SWF prior to inoculation would ensure that maximum amounts of silver would be leached before bacterial exposure as you previously described.

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c. Your testing adequately demonstrates that antibacterial preservative effectiveness is maintained for 24 hours. Please revise your 510(k) Summary and labeling as appropriate to reflect antibacterial preservative effectiveness of 24 hours, not 3 days.

2. If you choose to conduct additional testing (per Deficiency 1a, 1b above):

   Your test protocol appears to indicate that, following the addition of the neutralization broth, that bacteria are combined with the hot nutrient agar before it cools and solidifies. This method could lyse, inactivate, and/or hinder bacterial growth depending on temperature and distort your test results. Instead, please first prepare the nutrient agar plates and let them cool/solidify without adding bacteria. Prior to using these plates, place a control plate in the incubator for 24 hours to make sure that no contamination of other bacteria will grow. After performing your serial dilution on your samples, plate each dilution evenly on the surface of your nutrient agar plates using a plate spreader.

3. In your January 10, 2015 response, you stated that you revised your labeling to address Deficiency 8e of our September 19, 2014 letter. However, your submitted labeling did not reflect those revisions. Per Deficiency 8e, please remove the sentence "The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment" from your labeling (Section 13, p. 3).

4. You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

5. Your labeling contains symbols that are not accompanied by explanatory text. Please note 21 CFR 801.15(c)(1), which states that "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language." Thus, please revise your labeling such that all symbols are accompanied by explanatory text.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K141619/S002
Huizhou Foryou Medical Devices, Co., Ltd.
Trade Name: LUOFUCON Silver Foam Dressing

Dear Mr. Shen:

Thank you for your January 10, 2015 response to our September 19, 2014 letter requesting additional information. In reviewing this response, we identified several additional issues related to your antibacterial effectiveness testing. Our current policy is to try and resolve all remaining issues following issue of one letter requesting additional information in an interactive manner without placing the file on hold for a second time. However, because we did not initially communicate these issues to you in our September 19, 2014 letter, we are placing your file on a second hold to give you additional time to address these issues. To complete the review of your submission, please address the following deficiencies:

1. You stated that your device has "an antibacterial effective time of three days." However, after close inspection of your protocol, it is clear that contact between your device and bacteria was technically only assessed for 24 hours, regardless of time point. With regards to conditioning of the device prior to inoculation, only 100 µL simulated wound fluid (SWF) was applied to the device every 24 hours. Because the volume is smaller than what would be needed to saturate the sample, it is not clear that the conditioning protocol leached the maximum amount of silver from the dressing sample, as might occur during use. We believe your experimental design should ideally measure the device's ability to inhibit bacterial growth on the dressing under continuous exposure to bacteria over your claimed time period. We therefore do not believe that this testing is sufficient to support a claim antibacterial preservative effectiveness for 3 days. Please consider one of the following options:

    a. Please conduct additional testing with device samples and negative controls, inoculating all samples at time t=0 instead of at your specified time points and adding SWF as before. This will ensure that your preservative effectiveness testing adequately demonstrates resistance to bacterial colonization over 3 days, rather than 24 hours. We believe such an experimental design better emulates the clinically relevant scenario where your dressing remains on a wound for up to 3 days.

    b. Please conduct additional testing with device samples and controls with maximum leaching of silver over 3 days. In your January 10, 2015 response, you provided the results of silver leachability testing using samples that were saturated with SWF. Repeatedly saturating test samples with SWF prior to inoculation would ensure that maximum amounts of silver would be leached before bacterial exposure as you previously described.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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c. Your testing adequately demonstrates that antibacterial preservative effectiveness is maintained for 24 hours. Please revise your 510(k) Summary and labeling as appropriate to reflect antibacterial preservative effectiveness of 24 hours, not 3 days.

2. If you choose to conduct additional testing (per Deficiency 1a, 1b above):

   Your test protocol appears to indicate that, following the addition of the neutralization broth, that bacteria are combined with the hot nutrient agar before it cools and solidifies. This method could lyse, inactivate, and/or hinder bacterial growth depending on temperature and distort your test results. Instead, please first prepare the nutrient agar plates and let them cool/solidify without adding bacteria. Prior to using these plates, place a control plate in the incubator for 24 hours to make sure that no contamination of other bacteria will grow. After performing your serial dilution on your samples, plate each dilution evenly on the surface of your nutrient agar plates using a plate spreader.

3. In your January 10, 2015 response, you stated that you revised your labeling to address Deficiency 8e of our September 19, 2014 letter. However, your submitted labeling did not reflect those revisions. Per Deficiency 8e, please remove the sentence "The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment" from your labeling (Section 13, p. 3).

4. You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

5. Your labeling contains symbols that are not accompanied by explanatory text. Please note 21 CFR 801.15(c)(1), which states that "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language." Thus, please revise your labeling such that all symbols are accompanied by explanatory text.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

Huizhou Foryou Medical Devices Company, Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester Lane, Unit-B
Pennington, New Jersey 08534

Re: K141619
Trade/Device Name: Luofucon Silver Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 20, 2015
Received: March 24, 2015

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Silver serves as a preservative against bacterial growth in the dressing material

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial preservative agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	5-7 days

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Cortez, Karoll; Panguluri, Ramesh K
Cc: Claverie, Elizabeth F; Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Subject: K141619/S001 consult needed
Date: Tuesday, September 16, 2014 9:48:00 PM

Hi Karoll and Kapil,

Several weeks ago I requested a consult from you for K141619/S001, Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. I haven't received either of them yet, but I don't think I can be more flexible at this point. The file, for all intents and purposes, is due this Friday. If I don't hear from you, I will have to put a rough sketch together based on past consults from you and from INCB. However, I would much rather have your direct input on their microbiology test methods and results.

Can you provide your consult by 2 pm tomorrow (Wednesday)? If not, please let me know.

Thanks,
Peter
Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Claverie, Elizabeth F
Cc: Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Subject: K141619/S001 consult request
Date: Thursday, August 07, 2014 11:51:00 AM

Dear Liz,

I'm writing to request a microbiology consult from your branch for K141619/S001, Huizhou Foryou Medical Device's Luofucon Silver Foam Dressing.

It is a wound dressing containing silver. There are four variants of the device, but the base material is a polyurethane foam that's been fabricated with metallic silver particles encapsulated in the foam itself. They are claiming antimicrobial effectiveness against gram negative and gram positive bacteria within the dressing. I would appreciate your review of their antimicrobial efficacy protocols, data, and conclusions. They claim that "The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing."

It's a bit confusing, but the subject device is not the same as the company's Luofucon Silver PU Antibacterial Foam Dressing (K140954), in which ionic silver was apparently spray coated onto the surface of a foam dressing. Dr. Karoll Cortez was the consultant for that file.

Today is Day 15. If possible, I'd appreciate the consult completed by Friday, September 5, 2014 (Day 44). I've just assigned the consult to you in CTS, but I can be flexible with the due date.

Please let me know if you have any comments or questions about the file, and thank you for all your continued work with my branch's silver-containing devices.

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Peter Yang
To: cyshen@aol com
Cc: Yang, Peter (CDRH)
Subject: K141619/S001 is on Hold Pending Your Response
Date: Friday, September 19, 2014 3:27:44 PM
Attachments: K141619.S1.Deficiencies.pdf

September 19, 2014

We have reviewed your submission K141619/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K141619/S001 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is March 18, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Yang, Peter (CDRH)
To: Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Cc: Yoon, Diana (Diana.Yoon@fda.hhs.gov)
Subject: K141619/S001 review complete [AINN]
Date: Thursday, September 18, 2014 6:00:00 PM

Hi Jiyoung,

I've completed the review of K141619, Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. I recommend AI (AINN). Please find the memo on DocMan, along with the microbiology consult from Karoll Cortez of INCB.

I have not yet logged out in CTS, but that is because I'm waiting on the consult to be signed; it is not signed by her branch chief yet. Once that is done, I will update it accordingly.

Today, Thursday, September 18, is Day 57 – effectively it is due tomorrow, Friday, September 19.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Dang, Jiyoung M (Jiyoung.Dang@fda.hhs.gov)
Cc: Chang, Cynthia (Cynthia.Chang@fda.hhs.gov)
Subject: K141619/S001 RTA checklist completed (DAY 13) [RTAA]
Date: Tuesday, August 05, 2014 4:19:00 PM

Hi Jiyoung,

I've logged out K141619's RTA checklist in CTS as RTAA; they had a number of prior issues which they properly addressed in their new supplement.

The RTA checklist is **due TOMORROW;** that is to say, today, Tuesday, is **Day 13. Day 14 is Wednesday, August 6th**.

DocMan link:
http://docs.fda.gov/share/page/site/submissions/folder-details?nodeRef=workspace://SpacesStore/20dda1f7-bd77-4a81-aabc-171f39d009f9

Thanks,
Peter
Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Peter Yang
To: CYSHEN@AOL.COM
Cc: Yang, Peter (CDRH)
Subject: K141619/S001 was Accepted
Date: Wednesday, August 06, 2014 5:00:14 PM

August 6, 2014

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K141619/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Peter Yang.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Peter Yang
To: cyshen@aol com
Cc: Yang, Peter (CDRH)
Subject: K141619/S002 is on Hold Pending Your Response
Date: Monday, February 02, 2015 7:17:51 PM
Attachments: K141619.S2.Deficiencies.pdf

February 2, 2015

We have reviewed your submission K141619/S002 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K141619/S002 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is August 1, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Claverie, Elizabeth F
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K
Subject: k141619-consults
Date: Friday, August 08, 2014 11:46:55 AM
Importance: High

Hi Peter,
Kapil will mentor Karoll Cortez on this consult. Can you please place a bio risk consult in CTS for him as well.

Thank you,
Liz

Elizabeth F. Claverie-Williams, MS
Elizabeth F. Claverie-Williams, MS
CDR USPHS-CC, Microbiologist
Branch Chief, Infection Control Devices Branch
FDA/CDRH/ODE/DAGRID
10903 New Hampshire Ave.
White Oak, Bldg.66/Room 2508
Silver Spring, MD 20993
Office: 301-796-6298
Fax: 301-847-8109

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: mailer-daemon@fda.gov
To: Yang, Peter (CDRH)
Subject: Message undeliverable: K141619 was Refused
Date: Tuesday, July 01, 2014 4:27:45 PM

Your message did not reach some or all of the intended recipients.

Sent: Tue, 1 Jul 2014 16:20:09 -0400
Subject: K141619 was Refused

The following recipient(s) could not be reached:

official-K141619@docs.fda.gov
Error Type: SMTP
Remote server (10.172.80.188) issued an error.
hMailServer sent: .
Remote server replied: 554 The email address 'official-K141619@docs.fda.gov' does not reference a valid accessible node.

hMailServer

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cortez, Karoll
To: Yang, Peter (CDRH)
Subject: RE: CON145476 (K141619/S001)
Date: Tuesday, August 26, 2014 1:50:09 PM

Hi Peter,
Thanks for your response and clarifications.
I am aware of the due date; however, I thank you for the reminder.
Take care,
Karoll

From: Yang, Peter (CDRH)
Sent: Tuesday, August 26, 2014 12:13 PM
To: Cortez, Karoll
Subject: RE: CON145476 (K141619/S001)

Hi Karoll,

I was just looking at my documents in CTS and realized that I had neglected to answer your question! I'm terribly sorry for the long delay.

K141619/S001, Huizhou Foryou Medical Device's Luofucon Silver Foam Dressing, is a wound dressing containing silver. There are four variants of the device, but the base material is a polyurethane foam that's been fabricated with metallic silver particles encapsulated in the foam itself. They are claiming antimicrobial effectiveness against gram negative and gram positive bacteria within the dressing. I would appreciate your review of their antimicrobial efficacy protocols, data, and conclusions to know whether the protocols and data collected properly support their antimicrobial claims. They claim that "The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing."

It's a bit confusing, but the subject device is not the same as the their Luofucon Silver PU Antibacterial Foam Dressing (K140954), in which ionic silver was apparently spray coated onto the surface of a foam dressing. I think you were the consultant for that file as well.

Please let me know if you have any additional questions. I've set a due date of September 5, 2014.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

service you have received.

From: Cortez, Karoll
Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Hi, How are you?
I am an infectious disease doc , I do infection control consults.
However, I still need you give me a question to go by. What are your questions or instructions for me? Could you please articulate them?
Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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From: Cortez, Karoll
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Date: Friday, September 05, 2014 11:57:56 AM
Importance: High

Dear Peter,
Thanks for your clarifications and I know you gave me until today.
I am hoping I can ask for an extension, please.
I need to give my consult to Kapil and Liz prior to sending it to you, how much longer can you please give me?
Today is day 44. If you please also change the due date in CTS, please
Thanks
Karoll ☺

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Peter J. Yang, Ph.D.

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Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477

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Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
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10903 New Hampshire Ave.
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From: Yang, Peter (CDRH)
To: Cortez, Karoll
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Date: Friday, September 05, 2014 1:46:00 PM

Hi Karoll,

Thanks for your email. Sure, I can move the due date for you to next Wednesday, September 10 (Day 49). I have changed it in CTS.

Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Cortez, Karoll
Sent: Friday, September 05, 2014 11:58 AM
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Thanks for your clarifications and I know you gave me until today.
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Thanks
Karoll ☺

From: Yang, Peter (CDRH)
Sent: Tuesday, August 26, 2014 12:13 PM
To: Cortez, Karoll
Subject: RE: CON145476 (K141619/S001)

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Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

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From: Cortez, Karoll
Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Importance: High

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Hi, How are you?
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Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.

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Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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From: Cortez, Karoll
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Date: Friday, September 05, 2014 1:47:49 PM

Thanks Peter.
Have a great weekend
Karoll ☺

From: Yang, Peter (CDRH)
Sent: Friday, September 05, 2014 1:47 PM
To: Cortez, Karoll
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)

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Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Importance: High

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From: Yang, Peter (CDRH)
Sent: Tuesday, August 26, 2014 12:13 PM
To: Cortez, Karoll

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Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

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Importance: High

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Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
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From: Yang, Peter (CDRH)
To: Cortez, Karoll; Panguluri, Ramesh K
Cc: Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Date: Friday, September 12, 2014 10:39:00 AM

Hi Karoll and Kapil,

I hope you are doing well. I am writing to ask if you had completed your reviews of K141619/S001, Huizhou Foryou's Silver Foam Dressing. Today is **Day 51**, so there is still some time, but I would appreciate your consults as soon as you can reasonably complete them. Please let me know if I can assist. If you could give me a timeframe for when you might be able to complete them, that would be helpful as well so I can coordinate my own review.

Thanks,
Peter

Peter J. Yang, Ph.D.
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From: Cortez, Karoll
Sent: Friday, September 05, 2014 1:48 PM
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)

Thanks Peter.
Have a great weekend
Karoll ☺

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From: Cortez, Karoll
Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Hi, How are you?
I am an infectious disease doc , I do infection control consults.
However, I still need you give me a question to go by. What are your questions or instructions for me? Could you please articulate them?
Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
Ph (240)402-3791
Email: karoll.cortez@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Panguluri, Ramesh K
To: Yang, Peter (CDRH); Cortez, Karoll
Cc: Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Date: Friday, September 12, 2014 11:32:43 AM

Thank you Peter. Will do our best.

From: Yang, Peter (CDRH)
Sent: Friday, September 12, 2014 10:40 AM
To: Cortez, Karoll; Panguluri, Ramesh K
Cc: Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)

Hi Karoll and Kapil,

I hope you are doing well. I am writing to ask if you had completed your reviews of K141619/S001, Huizhou Foryou's Silver Foam Dressing. Today is **Day 51**, so there is still some time, but I would appreciate your consults as soon as you can reasonably complete them. Please let me know if I can assist. If you could give me a timeframe for when you might be able to complete them, that would be helpful as well so I can coordinate my own review.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
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From: Cortez, Karoll
Sent: Friday, September 05, 2014 1:48 PM
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)

Thanks Peter.
Have a great weekend
Karoll ☺

From: Yang, Peter (CDRH)
Sent: Friday, September 05, 2014 1:47 PM
To: Cortez, Karoll
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)

Hi Karoll,

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thanks for your email. Sure, I can move the due date for you to next Wednesday, September 10 (Day 49). I have changed it in CTS.

Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477

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From: Cortez, Karoll
Sent: Friday, September 05, 2014 11:58 AM
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Thanks for your clarifications and I know you gave me until today.
I am hoping I can ask for an extension, please.
I need to give my consult to Kapil and Liz prior to sending it to you, how much longer can you please give me?
Today is day 44. If you please also change the due date in CTS, please
Thanks
Karoll ☺

From: Yang, Peter (CDRH)
Sent: Tuesday, August 26, 2014 12:13 PM
To: Cortez, Karoll
Subject: RE: CON145476 (K141619/S001)

Hi Karoll,

I was just looking at my documents in CTS and realized that I had neglected to answer your question! I'm terribly sorry for the long delay.

K141619/S001, Huizhou Foryou Medical Device's Luofucon Silver Foam Dressing, is a wound dressing containing silver. There are four variants of the device, but the base material is a polyurethane foam that's been fabricated with metallic silver particles encapsulated in the foam itself. They are claiming antimicrobial effectiveness against gram negative and gram positive bacteria within the dressing. I would appreciate your review of their antimicrobial efficacy protocols, data, and conclusions to know whether the protocols and data collected properly support their antimicrobial claims. They claim that "The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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antibacterial effect in the dressing."

It's a bit confusing, but the subject device is not the same as the their Luofucon Silver PU Antibacterial Foam Dressing (K140954), in which ionic silver was apparently spray coated onto the surface of a foam dressing. I think you were the consultant for that file as well.

Please let me know if you have any additional questions. I've set a due date of September 5, 2014.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Cortez, Karoll
Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Hi, How are you?
I am an infectious disease doc , I do infection control consults.
However, I still need you give me a question to go by. What are your questions or instructions for me? Could you please articulate them?
Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Yang, Peter (CDRH)
To: Cortez, Karoll
Subject: RE: CON145476 (K141619/S001)
Date: Tuesday, August 26, 2014 12:12:00 PM

Hi Karoll,

I was just looking at my documents in CTS and realized that I had neglected to answer your question! I'm terribly sorry for the long delay.

K141619/S001, Huizhou Foryou Medical Device's Luofucon Silver Foam Dressing, is a wound dressing containing silver. There are four variants of the device, but the base material is a polyurethane foam that's been fabricated with metallic silver particles encapsulated in the foam itself. They are claiming antimicrobial effectiveness against gram negative and gram positive bacteria within the dressing. I would appreciate your review of their antimicrobial efficacy protocols, data, and conclusions to know whether the protocols and data collected properly support their antimicrobial claims. They claim that "The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing."

It's a bit confusing, but the subject device is not the same as the their Luofucon Silver PU Antibacterial Foam Dressing (K140954), in which ionic silver was apparently spray coated onto the surface of a foam dressing. I think you were the consultant for that file as well.

Please let me know if you have any additional questions. I've set a due date of September 5, 2014.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
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From: Cortez, Karoll
Sent: Wednesday, August 13, 2014 1:41 PM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Gutala, Sreekanth; Cunningham, Terrell
Subject: CON145476 (K141619/S001)
Importance: High

Dear Peter,
Hi, How are you?

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I am an infectious disease doc , I do infection control consults.
However, I still need you give me a question to go by. What are your questions or instructions for me? Could you please articulate them?
Thank you so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Yang, Peter (CDRH)
To: Krause, David
Subject: RE: DUE TOMORROW - K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 01, 2014 4:33:00 PM

Hi David,

Thank you for logging it out today – I apologize for the added pressure.

Sincerely,
Peter

From: Krause, David
Sent: Tuesday, July 01, 2014 4:22 PM
To: Dang, Jiyoung M; Yang, Peter (CDRH)
Cc: Ashar, Binita S; Warfield, Diana L.; Adams, Yolanda
Subject: RE: DUE TOMORROW - K141619 RTA checklist completed [RTA1]

I have concurred on the RTA1 recommendation in CTS and on the RTA review form. Please move the document folder to the DSD RTA1 bin. Thanks.

David

David Krause, PhD
Deputy Director
Division of Surgical Devices
CDRH/ODE

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From: Dang, Jiyoung M
Sent: Tuesday, July 01, 2014 4:16 PM
To: Ashar, Binita S; Krause, David
Cc: Yang, Peter (CDRH)
Subject: DUE TOMORROW - K141619 RTA checklist completed [RTA1]

K141619
Rta recommendation – RTA1
Rta due – TOMORROW (7/2)
Checklist on docman

DocMan: http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Krause, David
To: Dang, Jiyoung M; Yang, Peter (CDRH)
Cc: Ashar, Binita S; Warfield, Diana L.; Adams, Yolanda
Subject: RE: DUE TOMORROW - K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 01, 2014 4:21:45 PM

I have concurred on the RTA1 recommendation in CTS and on the RTA review form. Please move the document folder to the DSD RTA1 bin. Thanks.

David

David Krause, PhD
Deputy Director
Division of Surgical Devices
CDRH/ODE

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From: Dang, Jiyoung M
Sent: Tuesday, July 01, 2014 4:16 PM
To: Ashar, Binita S; Krause, David
Cc: Yang, Peter (CDRH)
Subject: DUE TOMORROW - K141619 RTA checklist completed [RTA1]

K141619
Rta recommendation – RTA1
Rta due – TOMORROW (7/2)
Checklist on docman

DocMan: http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Krause, David
To: Dang, Jiyoung M
Cc: Yang, Peter (CDRH)
Subject: RE: DUE TOMORROW - ready for division review/concurrence - K141619/S001 - RTAA
Date: Wednesday, August 06, 2014 4:53:58 PM

Done.

David Krause, PhD
Deputy Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

10903 New Hampshire Avenue
Bldg. 66, Room G412
Phone: 301.796.6970
Email: david.krause@fda.hhs.gov

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From: Dang, Jiyoung M
Sent: Wednesday, August 06, 2014 3:00 PM
To: Krause, David
Cc: Yang, Peter (CDRH)
Subject: DUE TOMORROW - ready for division review/concurrence - K141619/S001 - RTAA

DUE TOMORROW

K141619/S001
Rta recommendation – RTAA
Checklist on docman

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: cyshen@aol.com
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619 - interactive review
Date: Thursday, April 02, 2015 1:36:11 PM
Attachments: Section_04_Indications_for_Use_Re.pdf
Section_5_510k_summary_Re_4.pdf

Dear Dr Yang:

Thank you very much for your email.

The 510K Summary and Indications for Use have been revised and attached for your kind review

Kind regards

Charles Shen

-----Original Message-----
From: Yang, Peter (CDRH) (CDRH) <Peter.Yang@fda.hhs.gov>
To: cyshen <cyshen@aol.com>
Cc: K141619 <K141619@docs.fda.gov>
Sent: Wed, Apr 1, 2015 4:11 pm
Subject: RE: K141619 - interactive review

Hi Charles,

Thanks for your response earlier today. However, we request your response to the following deficiencies via email by tomorrow, Thursday, April 2, 2015 at 4 pm Eastern.

With regards to your 510(k) Summary:
Per deficiency 3a, please remove â€œSection 5: 510(k) Summary: Prescriptionâ€ from the header and footer on each page.
Per deficiency 2, which referenced the User Manual, please revise â€œSilver for antibacterial effectâ€ to â€œSilver for antibacterial preservative effectâ€ in Table 5.1.
Per deficiency 3e, please remove references to promotional material from Table 5.2.
Per deficiency 3f, please remove â€œAATCC 100-2004 was used to evaluate the antibacterial activity of the product.â€ from the 510(k) summary. Referencing AATCC 100-2004 implies FDA recognition of the standard; however, FDA does not recognize the AATCC 100-2004 standard.

Additionally, please note that Form FDA 3881, the Indications for Use statement, was updated in August 2014. It is available at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf

We recommend that you also provide an updated Indications for Use document using the updated form, which does not require CDRH concurrence. No other changes to the indications for use are needed.

We request your response to the following deficiencies via email by tomorrow, Thursday, April 2, 2015 at 5 pm Eastern. Please email with questions as needed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2
301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: cyshen@aol.com [mailto:cyshen@aol.com]
Sent: Wednesday, April 01, 2015 9:58 AM
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619 - interactive review

Dear Dr Yang:

Thank you very much for your email

The revisions have been made and on Section 4, Section 5, and Section 13. Please find the attached.

Please let me know if something else is needed.

Kind regards

Charles Shen

> Dear Mr. Shen,
>
> Thank you for your March 20, 2015 response to our February 2, 2015 letter. We are currently in the interactive review process and have but a few days to complete review; as such, we request your response to the following deficiencies via email by tomorrow, Wednesday, April 1, 2015 at 12 pm Eastern.
>
> 1. Please revise your indications for use in your labeling, 510(k) Summary, and Indications for Use statement to remove the statement regarding silver serving as a preservative. We request this to facilitate comparison of the IFU with the predicate device and to limit the indications for use to the conditions that your device will treat. Other language discussing silver in your User Manual and 510(k) Summary (given the revisions requested below) remain appropriate.
> 2. In your User Manual labeling, please revise Ã¢â‚¬Å“Proven Antibacterial EffectivenessÃ¢â‚¬Â to Ã¢â‚¬Å“Proven Antibacterial Preservative Effectiveness.Ã¢â‚¬Â We request this change to clarify that the role of silver is to act as a preservative.
> 3. Please revise your 510(k) Summary as follows:
>
>   a. Please remove Section numbers and references to other areas of your submission. The 510(k) Summary is a standalone document.
>   b. Please update the Summary Date.
>   c. Please move the Ã¢â‚¬Å“Silver serves as a preservativeÃ¢â‚¬Â¦Ã¢â‚¬Â

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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statement from the Indications for Use statement to the Product Information section above it. This is so that your product information can be placed in the proper context of silver as a preservative.

d. Please correct typos in the Predicate Indications for Use in Table 5.1.
e. When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
f. Your statements regarding AATCC 100 imply that testing was done above and beyond what was required to establish substantial equivalence. Additionally, the term Ã¢â‚¬Å“99.99%Ã¢â‚¬Â does not accurately reflect your testing. Please revise the paragraph discussing AATCC-100 to state Ã¢â‚¬Å“To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.Ã¢â‚¬Â
g. The next paragraph following discussion of AATCC 100 references promotional material as discussed above. The statement in this paragraph regarding dressing changes is not accurate, as the dressing should be changed at least every three days, and because the device is not be used Ã¢â‚¬Å“for antibacterial purpose.Ã¢â‚¬Â Thus, please remove this paragraph, which begins Ã¢â‚¬Å“The 510(k) Summary of the predicate device lists effective duration of 5-7 daysÃ¢â‚¬Â¦Ã¢â‚¬Â from your 510(k) Summary.

Please respond to these deficiencies by providing a revised Indications for Use statement, 510(k) Summary, and User Manual via email by tomorrow, Wednesday, April 1, 2015, at 12 pm Eastern. If you have any questions, please email as needed.

Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE

White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

-----Original Message-----
From: Yang, Peter (CDRH) (CDRH) <Peter.Yang@fda.hhs.gov>
To: cyshen <cyshen@aol.com>
Cc: K141619 <K141619@docs.fda.gov>

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Sent: Tue, Mar 31, 2015 11:31 am
Subject: K141619 - interactive review

Dear Mr. Shen,

Thank you for your March 20, 2015 response to our February 2, 2015 letter. We are currently in the interactive review process and have but a few days to complete review; as such, we request your response to the following deficiencies via email by tomorrow, Wednesday, April 1, 2015 at 12 pm Eastern.

1. Please revise your indications for use in your labeling, 510(k) Summary, and Indications for Use statement to remove the statement regarding silver serving as a preservative. We request this to facilitate comparison of the IFU with the predicate device and to limit the indications for use to the conditions that your device will treat. Other language discussing silver in your User Manual and 510(k) Summary (given the revisions requested below) remain appropriate.
2. In your User Manual labeling, please revise Ã¢â‚¬Å“Proven Antibacterial EffectivenessÃ¢â‚¬Â to Ã¢â‚¬Å“Proven Antibacterial Preservative Effectiveness.Ã¢â‚¬Â We request this change to clarify that the role of silver is to act as a preservative.
3. Please revise your 510(k) Summary as follows:

    a. Please remove Section numbers and references to other areas of your submission. The 510(k) Summary is a standalone document.
    b. Please update the Summary Date.
    c. Please move the Ã¢â‚¬Å“Silver serves as a preservativeÃ¢â‚¬Â¦Ã¢â‚¬Â statement from the Indications for Use statement to the Product Information section above it. This is so that your product information can be placed in the proper context of silver as a preservative.
    d. Please correct typos in the Predicate Indications for Use in Table 5.1.
    e. When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
    f. Your statements regarding AATCC 100 imply that testing was done above and beyond what was required to establish substantial equivalence. Additionally, the term Ã¢â‚¬Å“99.99%Ã¢â‚¬Â does not accurately reflect your testing. Please revise the paragraph discussing AATCC-100 to state Ã¢â‚¬Å“To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.Ã¢â‚¬Â
    g. The next paragraph following discussion of AATCC 100 references promotional material as discussed above. The statement in this paragraph regarding dressing changes is not accurate, as the dressing <u>should</u> be changed at least every three days, and because the device is not be used Ã¢â‚¬Å“for antibacterial purpose.Ã¢â‚¬Â Thus, please remove this paragraph, which begins Ã¢â‚¬Å“The 510(k) Summary of the predicate device lists effective duration of 5-7 daysÃ¢â‚¬Â¦Ã¢â‚¬Â from your 510(k) Summary.

Please respond to these deficiencies by providing a revised Indications for Use statement, 510(k) Summary, and User Manual via email by tomorrow, Wednesday, April 1, 2015, at 12 pm Eastern. If you have any questions, please email as needed.

Sincerely,
Peter Yang

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE

White Oak Building #66, Room G435
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Silver Spring, MD 20993
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Email: peter.yang@fda.hhs.gov

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From: Yang, Peter (CDRH)
To: "cyshen@aol.com"
Cc: K141619@docs.fda.gov
Subject: RE: K141619 - interactive review
Date: Thursday, April 02, 2015 1:38:00 PM

Dear Mr. Shen,

Thanks for your response. At this time, we do not have any further questions.

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: cyshen@aol.com [mailto:cyshen@aol.com]
Sent: Thursday, April 02, 2015 1:35 PM
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619 - interactive review

Dear Dr Yang:

Thank you very much for your email.

The 510K Summary and Indications for Use have been revised and attached for your kind review

Kind regards

Charles Shen

-----Original Message-----
From: Yang, Peter (CDRH) (CDRH) <Peter.Yang@fda.hhs.gov>
To: cyshen <cyshen@aol.com>
Cc: K141619 <K141619@docs.fda.gov>
Sent: Wed, Apr 1, 2015 4:11 pm
Subject: RE: K141619 - interactive review

Hi Charles,

Thanks for your response earlier today. However, we request your response to the following deficiencies via email by tomorrow, Thursday, April 2, 2015 at 4 pm Eastern.

With regards to your 510(k) Summary:
Per deficiency 3a, please remove â€œSection 5: 510(k) Summary: Prescriptionâ€ from the header

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and footer on each page.
Per deficiency 2, which referenced the User Manual, please revise â€œSilver for antibacterial effectâ€ to â€œSilver for antibacterial preservative effectâ€ in Table 5.1.
Per deficiency 3e, please remove references to promotional material from Table 5.2.
Per deficiency 3f, please remove â€œAATCC 100-2004 was used to evaluate the antibacterial activity of the product.â€ from the 510(k) summary. Referencing AATCC 100-2004 implies FDA recognition of the standard; however, FDA does not recognize the AATCC 100-2004 standard.

Additionally, please note that Form FDA 3881, the Indications for Use statement, was updated in August 2014. It is available at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf

We recommend that you also provide an updated Indications for Use document using the updated form, which does not require CDRH concurrence. No other changes to the indications for use are needed.

We request your response to the following deficiencies via email by tomorrow, Thursday, April 2, 2015 at 5 pm Eastern. Please email with questions as needed.

Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477

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From: cyshen@aol.com [mailto:cyshen@aol.com]
Sent: Wednesday, April 01, 2015 9:58 AM
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619 - interactive review

Dear Dr Yang:

Thank you very much for your email

The revisions have been made and on Section 4, Section 5, and Section 13. Please find the attached.

Please let me know if something else is needed.

Kind regards

Charles Shen

> Dear Mr. Shen,

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Please revise your indications for use in your labeling, 510(k) Summary, and Indications for Use statement to remove the statement regarding silver serving as a preservative. We request this to facilitate comparison of the IFU with the predicate device and to limit the indications for use to the conditions that your device will treat. Other language discussing silver in your User Manual and 510(k) Summary (given the revisions requested below) remain appropriate.
2. In your User Manual labeling, please revise Ã¢â‚¬Å“Proven Antibacterial EffectivenessÃ¢â‚¬Â to Ã¢â‚¬Å“Proven Antibacterial Preservative Effectiveness.Ã¢â‚¬Â We request this change to clarify that the role of silver is to act as a preservative.
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    b. Please update the Summary Date.
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    d. Please correct typos in the Predicate Indications for Use in Table 5.1.
    e. When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
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Email: peter.yang@fda.hhs.gov

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To: cyshen <cyshen@aol.com>
Cc: K141619 <K141619@docs.fda.gov>
Sent: Tue, Mar 31, 2015 11:31 am
Subject: K141619 - interactive review

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From: cyshen@aol.com
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619 - interactive review
Date: Wednesday, April 01, 2015 9:58:36 AM
Attachments: Section_04_Indications_for_Use.pdf
Section_5_510k_summary_Re_3.pdf
Section_13_Labeling_RE4.pdf

Dear Dr Yang:

Thank you very much for your email

The revisions have been made and on Section 4, Section 5, and Section 13. Please find the attached.

Please let me know if something else is needed.

Kind regards

Charles Shen

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Email: peter.yang@fda.hhs.gov
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To: cyshen <cyshen@aol.com>
Cc: K141619 <K141619@docs.fda.gov>
Sent: Tue, Mar 31, 2015 11:31 am
Subject: K141619 - interactive review

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3. Please revise your 510(k) Summary as follows:
    a. Please remove Section numbers and references to other areas of your submission. The 510(k) Summary is a standalone document.
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From: Yang, Peter (CDRH)
To: "cyshen@aol.com"
Cc: K141619@docs.fda.gov
Subject: RE: K141619 - interactive review
Date: Wednesday, April 01, 2015 4:11:00 PM

Hi Charles,

Thanks for your response earlier today. However, we request your response to the following deficiencies via email by tomorrow, Thursday, April 2, 2015 at 4 pm Eastern.

With regards to your 510(k) Summary:

1. Per deficiency 3a, please remove "Section 5: 510(k) Summary: Prescription" from the header and footer on each page.
2. Per deficiency 2, which referenced the User Manual, please revise "Silver for antibacterial effect" to "Silver for antibacterial preservative effect" in Table 5.1.
3. Per deficiency 3e, please remove references to promotional material from Table 5.2.
4. Per deficiency 3f, please remove "AATCC 100-2004 was used to evaluate the antibacterial activity of the product." from the 510(k) summary. Referencing AATCC 100-2004 implies FDA recognition of the standard; however, FDA does not recognize the AATCC 100-2004 standard.

Additionally, please note that Form FDA 3881, the Indications for Use statement, was updated in August 2014. It is available at:
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Subject: Re: K141619 - interactive review

Dear Dr Yang:

Thank you very much for your email

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Please let me know if something else is needed.

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e. When comparing between your device and the predicate device (e.g., Table 5.1, footnote a), please remove references to promotional material. This is because such material has not been reviewed by the FDA. Instead, please reference information from the 510(k) Summary of the predicate device.
f. Your statements regarding AATCC 100 imply that testing was done above and beyond what was required to establish substantial equivalence. Additionally, the term â€œ99.99%â€ does not accurately reflect your testing. Please revise the paragraph discussing AATCC-100 to state â€œTo support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.â€
g. The next paragraph following discussion of AATCC 100 references promotional material as discussed above. The statement in this paragraph regarding dressing changes is not accurate, as the dressing should be changed at least every three days, and because the device is not be used â€œfor antibacterial purpose.â€ Thus, please remove this paragraph, which begins â€œThe 510(k) Summary of the predicate device lists effective duration of 5-7 daysâ€¦â€ from your 510(k) Summary.

Please respond to these deficiencies by providing a revised Indications for Use statement, 510(k) Summary, and User Manual via email by tomorrow, Wednesday, April 1, 2015, at 12 pm Eastern. If you have any questions, please email as needed.

Sincerely,
Peter Yang

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE

White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Claverie, Elizabeth F
To: Yang, Peter (CDRH); Cortez, Karoll
Subject: Re: K141619 Peter"s consult
Date: Friday, September 19, 2014 6:46:09 AM

You are welcomed!

From: Yang, Peter (CDRH)
Sent: Thursday, September 18, 2014 11:36 PM Eastern Standard Time
To: Claverie, Elizabeth F; Cortez, Karoll
Subject: RE: K141619 Peter's consult

Hi all,

Thanks to you both! Appreciate your hard work on this.

Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Claverie, Elizabeth F
Sent: Thursday, September 18, 2014 10:42 PM
To: Cortez, Karoll
Cc: Yang, Peter (CDRH)
Subject: Re: K141619 Peter's consult

Thank you! I will sign in the morning.
Peter please feel free to move forward with the deficiencies.

From: Cortez, Karoll
Sent: Thursday, September 18, 2014 10:32 PM Eastern Standard Time
To: Claverie, Elizabeth F
Cc: Yang, Peter (CDRH)
Subject: FW: K141619 Peter's consult

Liz, this is the consult for your signature.
Peter, you already have this memo in word, but here it is again for both of your convenience.
Thank you so much for your patience.
Good night
Karoll

From: Cortez, Karoll
Sent: Thursday, September 18, 2014 3:40 PM

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

To: Claverie, Elizabeth F
Subject: K141619 Peter's consult

For your signature
Thanks so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
CDRH/ODE/DAGRID
White Oak, Bldg. 66 Rm 2463
10903 New Hampshire Ave.
Silver Spring, MD 20993
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Email: karoll.cortez@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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From: Claverie, Elizabeth F
To: Cortez, Karoll
Cc: Yang, Peter (CDRH)
Subject: Re: K141619 Peter"s consult
Date: Thursday, September 18, 2014 10:41:59 PM

Thank you! I will sign in the morning.
Peter please feel free to move forward with the deficiencies.

From: Cortez, Karoll
Sent: Thursday, September 18, 2014 10:32 PM Eastern Standard Time
To: Claverie, Elizabeth F
Cc: Yang, Peter (CDRH)
Subject: FW: K141619 Peter's consult

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Karoll

From: Cortez, Karoll
Sent: Thursday, September 18, 2014 3:40 PM
To: Claverie, Elizabeth F
Subject: K141619 Peter's consult

For your signature
Thanks so much
Karoll

Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Claverie, Elizabeth F; Cortez, Karoll
Subject: RE: K141619 Peter"s consult
Date: Thursday, September 18, 2014 11:36:00 PM

Hi all,

Thanks to you both! Appreciate your hard work on this.

Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Claverie, Elizabeth F
Sent: Thursday, September 18, 2014 10:42 PM
To: Cortez, Karoll
Cc: Yang, Peter (CDRH)
Subject: Re: K141619 Peter's consult

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Karoll J. Cortez, M.D., M.H.S., F.A.C.P.
Infectious Disease Specialist
Infection Control Devices Branch
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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Dang, Jiyoung M
Subject: RE: K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 01, 2014 11:54:00 AM

Hi Jiyoung,

I made your suggested edits, scooted in before DocMan meets the fail whale, and logged it out in CTS. They actually didn't say whether there were prior submissions, so I simply asked them to clarify whether there were any.

DocMan: http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Dang, Jiyoung M
Sent: Monday, June 30, 2014 10:33 PM
To: Yang, Peter (CDRH)
Subject: RE: K141619 RTA checklist completed [RTA1]

Hi Peter,

While I agree with most of the rejection items, I don't know about two of these items. please read my comments below and post a revised checklist on docman. Also, please log out in cts.

Thanks,
Jiyoung

Question 5: since both positions are within the company, I see this not as a RTA reject issue. It would appear that they've provided a truthful and accurate statement, therefore, please check 'yes' for this item.

Question 9: just as a clarification, did they state that there were no prior submissions or were they silent on this item? Or did they state that there was prior related submissions?
If the sponsor was silent, then I would proceed with checking 'no' for Q9 and leaving Q9a blank (or checking n/a since you can't uncheck a checked question) and revising the comment to simply ask

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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them to clarify whether or not there have been prior communications for this same device.
If there was some statement and you think its incomplete or incorrect (as is suggested by your comment), I don't think this would make it as a reject item. I would proceed with checking 'yes' for Q9.

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

White Oak Building #66, Room G406 | 10903 New Hampshire Avenue |Silver Spring, Maryland 20993-0002
301.796.6970 (phone - main) | 301.796.6437 (phone - direct line) | 301.595.7851 (fax)
jiyoung.dang@fda.hhs.gov

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From: Yang, Peter (CDRH)
Sent: Monday, June 30, 2014 2:44 PM
To: Dang, Jiyoung M
Subject: K141619 RTA checklist completed [RTA1]

Hi Jiyoung,

I've completed the RTA checklist for K141619 – Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. The submission lacks several elements, hence RTA1. Today, Monday, is FDA Day **13**.

Please let me know if you have any comments or questions. The checklist can be found on DocMan:

http://docs.fda.gov/share/page/site/submissions/document-details?nodeRef=workspace://SpacesStore/2e0f88cd-c6e2-4b6e-b7b1-93b504dfc19d

Thanks,
Peter

Peter J. Yang, Ph.D.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Email: peter.yang@fda.hhs.gov
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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Dang, Jiyoung M
Subject: RE: K141619 RTA checklist completed [RTA1]
Date: Tuesday, July 01, 2014 12:15:00 PM

Hi Jiyoung,

The RTA checklist is now on the L drive:

L:\ODE\DSD\PRSB\PJY\K141619 - Quick-Med Stay Fresh Wound Dressing\

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Yang, Peter (CDRH)
Sent: Tuesday, July 01, 2014 11:55 AM
To: Dang, Jiyoung M
Subject: RE: K141619 RTA checklist completed [RTA1]

Hi Jiyoung,

I made your suggested edits, scooted in before DocMan meets the fail whale, and logged it out in CTS. They actually didn't say whether there were prior submissions, so I simply asked them to clarify whether there were any.

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Thanks,
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Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

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From: Dang, Jiyoung M

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Yang, Peter (CDRH)
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Jiyoung

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Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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From: Yang, Peter (CDRH)
Sent: Monday, June 30, 2014 2:44 PM
To: Dang, Jiyoung M
Subject: K141619 RTA checklist completed [RTA1]

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Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
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10903 New Hampshire Avenue
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Dang, Jiyoung M
To: Yang, Peter (CDRH)
Subject: RE: K141619 RTA checklist completed [RTA1]
Date: Monday, June 30, 2014 10:32:57 PM

Hi Peter,

While I agree with most of the rejection items, I don't know about two of these items. please read my comments below and post a revised checklist on docman. Also, please log out in cts.

Thanks,
Jiyoung

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Thanks,
Peter

Peter J. Yang, Ph.D.
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Claverie, Elizabeth F
To: Yang, Peter (CDRH); Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M; Gutala, Sreekanth
Subject: Re: K141619/S001 consult needed
Date: Wednesday, September 17, 2014 6:55:31 AM

Thank you very much Peter!

I am out of the office this morning, but should be in late this afternoon. Kapil, Sreekanth or I will work towards getting the consult signed out and to you today.

Thank you,
Liz

From: Yang, Peter (CDRH)
Sent: Tuesday, September 16, 2014 11:44 PM Eastern Standard Time
To: Claverie, Elizabeth F; Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M
Subject: RE: K141619/S001 consult needed

Hi Liz, Karoll, and Kapil,

Thanks for your email. Thanks as well for the clarification regarding Kapil's consult.

I'm also fairly new, so I understand how involved the first few files are in terms of effort and training. We have a number of people newly on board as well, so it has been insightful to see the training process from both sides.

If I reiterate it too much it may unavoidably lose its meaning, but I am continually appreciating Infection Control's critical role and I understand that everyone has truly immense workloads. I have also worked with Karoll and Kapil in the past; your insight and experience have been invaluable to a new reviewer like me. Hence the consults. ☺ Thank you once again for all your hard work.

Please let me know if I can be of assistance in any way.

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Claverie, Elizabeth F

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Sent: Tuesday, September 16, 2014 11:13 PM
To: Yang, Peter (CDRH); Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M
Subject: Re: K141619/S001 consult needed

Hi Peter,

Thank you the email. I understand an appreciate your email.

FYI: Kapil is not your consultant. I asked you to place a consult in CTS to cover and track the work he is doing with training the new reviewers and/or medical officer in this case Karoll.

Karoll is your consultant.
I worked with Karoll today to draft several deficiencies we will forward to you. She should be wrapping her consult up tomorrow. She has to send it back through me afterwards and I will then sign it out and get it to you ASAP tomorrow.

Again thank you and as I get all of our new people trained we hope to move faster.

Please cintact me if you havd any questions or concerns.

Jiyoung thank you as well.

With respect,
Liz

From: Yang, Peter (CDRH)
Sent: Tuesday, September 16, 2014 09:48 PM Eastern Standard Time
To: Cortez, Karoll; Panguluri, Ramesh K
Cc: Claverie, Elizabeth F; Dang, Jiyoung M
Subject: K141619/S001 consult needed

Hi Karoll and Kapil,

Several weeks ago I requested a consult from you for K141619/S001, Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. I haven't received either of them yet, but I don't think I can be more flexible at this point. The file, for all intents and purposes, is due this Friday. If I don't hear from you, I will have to put a rough sketch together based on past consults from you and from INCB. However, I would much rather have your direct input on their microbiology test methods and results.

Can you provide your consult by 2 pm tomorrow (Wednesday)? If not, please let me know.

Thanks,
Peter
Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Dang, Jiyoung M
To: Cortez, Karoll; Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Panguluri, Ramesh K
Subject: RE: K141619/S001 consult needed
Date: Wednesday, September 17, 2014 5:42:49 AM

Thanks Everyone!

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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From: Cortez, Karoll
Sent: Wednesday, September 17, 2014 4:18 AM
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Dang, Jiyoung M; Panguluri, Ramesh K
Subject: RE: K141619/S001 consult needed

Dear Peter:
You will have your memo today. It took a long time because it is a difficult and disorganized file with multiple deficiencies. I am sorry it has taken so long. You can copy/paste the consult to your memo, and can tell you that this submission will need to be on hold until the firm addresses the micro issues.
Thank you for your patience and flexibility.
Karoll

From: Yang, Peter (CDRH)
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Cc: Claverie, Elizabeth F; Dang, Jiyoung M
Subject: K141619/S001 consult needed

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From: Cortez, Karoll
To: Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Dang, Jiyoung M; Panguluri, Ramesh K
Subject: RE: K141619/S001 consult needed
Date: Wednesday, September 17, 2014 4:18:21 AM

Dear Peter:
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Karoll

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Sent: Tuesday, September 16, 2014 9:49 PM
To: Cortez, Karoll; Panguluri, Ramesh K
Cc: Claverie, Elizabeth F; Dang, Jiyoung M
Subject: K141619/S001 consult needed

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From: Claverie, Elizabeth F
To: Dang, Jiyoung M; Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K; Cortez, Karoll; Murray III, Clarence
Subject: RE: K141619/S001 consult needed
Date: Wednesday, September 17, 2014 6:32:32 PM
Importance: High

Peter and Jiyoung,

Thank you all for your patience with us!

I have reviewed Karoll's consult and it is almost ready to go. I need to work with her a little tomorrow morning to set the deficiencies up in 4 part harmony.
Please excuse our not meeting your deadline today Peter. We will get it to you late morning tomorrow in a fashion whereby you should if you wish, be able to cut and paste the deficiencies.

Again thank you and let me know if you have any questions or concerns.

Jiyoung sorry this is so late.

With respect,
Liz

Elizabeth F. Claverie-Williams, MS
Elizabeth F. Claverie-Williams, MS
CDR USPHS-CC, Microbiologist
Branch Chief, Infection Control Devices Branch
FDA/CDRH/ODE/DAGRID
10903 New Hampshire Ave.
White Oak, Bldg.66/Room 2508
Silver Spring, MD 20993
Office: 301-796-6298
Fax: 301-847-8109

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https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=435&E=&S=E

From: Dang, Jiyoung M
Sent: Wednesday, September 17, 2014 5:43 AM
To: Cortez, Karoll; Yang, Peter (CDRH)
Cc: Claverie, Elizabeth F; Panguluri, Ramesh K
Subject: RE: K141619/S001 consult needed

Thanks Everyone!

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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10903 New Hampshire Avenue
Silver Spring, MD 20993

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From: Claverie, Elizabeth F
To: Yang, Peter (CDRH); Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M
Subject: Re: K141619/S001 consult needed
Date: Tuesday, September 16, 2014 11:12:35 PM

Hi Peter,

Thank you the email. I understand an appreciate your email.

FYI: Kapil is not your consultant. I asked you to place a consult in CTS to cover and track the work he is doing with training the new reviewers and/or medical officer in this case Karoll.

Karoll is your consultant.
I worked with Karoll today to draft several deficiencies we will forward to you. She should be wrapping her consult up tomorrow. She has to send it back through me afterwards and I will then sign it out and get it to you ASAP tomorrow.

Again thank you and as I get all of our new people trained we hope to move faster.

Please cintact me if you havd any questions or concerns.

Jiyoung thank you as well.

With respect,
Liz

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Sent: Tuesday, September 16, 2014 09:48 PM Eastern Standard Time
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Subject: K141619/S001 consult needed

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Peter J. Yang, Ph.D.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Yang, Peter (CDRH)
To: Claverie, Elizabeth F; Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M
Subject: RE: K141619/S001 consult needed
Date: Tuesday, September 16, 2014 11:44:00 PM

Hi Liz, Karoll, and Kapil,

Thanks for your email. Thanks as well for the clarification regarding Kapil's consult.

I'm also fairly new, so I understand how involved the first few files are in terms of effort and training. We have a number of people newly on board as well, so it has been insightful to see the training process from both sides.

If I reiterate it too much it may unavoidably lose its meaning, but I am continually appreciating Infection Control's critical role and I understand that everyone has truly immense workloads. I have also worked with Karoll and Kapil in the past; your insight and experience have been invaluable to a new reviewer like me. Hence the consults. ☺ Thank you once again for all your hard work.

Please let me know if I can be of assistance in any way.

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Claverie, Elizabeth F
Sent: Tuesday, September 16, 2014 11:13 PM
To: Yang, Peter (CDRH); Cortez, Karoll; Panguluri, Ramesh K
Cc: Dang, Jiyoung M
Subject: Re: K141619/S001 consult needed

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FYI: Kapil is not your consultant. I asked you to place a consult in CTS to cover and track the work he is doing with training the new reviewers and/or medical officer in this case Karoll.

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Cc: Claverie, Elizabeth F; Dang, Jiyoung M
Subject: K141619/S001 consult needed

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Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cyshen@aol.com
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 is on Hold Pending Your Response
Date: Monday, January 05, 2015 8:18:14 AM

Dear Dr Yang:

Thank you very much for for providing your deficiency comments on K141619/S001. We are working hard to make all the corrections and resolve all the issues raised by FDA.

Here we have a couple of questons regarding your deficiency letter, can you please kindly enlighten us?

(1) In comment 5e, you mentioned "the protocol itself is confusing and not easily understood.". Can you please kindly be more specific as to which part of the protocol is confusing? So we can target and revise these parts more specifically?

(2) In commment 5f, you mentioned " You tested multiple sample groups with varying species of bacteria;...". When you say "sample groups", dis you refer to group of day 1 test samples and group of day-3 test samples?

Can you please kindly enlighten us?

Thank you very much

Charles Shen

In a message dated 9/19/2014 2:27:45 P.M. Eastern Standard Time, peter.yang@fda.hhs.gov writes:

> September 19, 2014
>
> We have reviewed your submission K141619/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.
>
> Please submit your response, referencing the submission number K141619/S001 to:
>
> U.S. Food and Drug Administration
> Center for Devices and Radiological Health
> Document Control Center - WO66-G609
> 10903 New Hampshire Avenue
> Silver Spring, MD 20993-0002
>
> Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.
>
> Your response is due within 180 days from the date of this request, which is March 18, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.
>
> You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.
>
> If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.
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> Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "Cyshen@aol.com"
Subject: RE: K141619/S001 is on Hold Pending Your Response
Date: Tuesday, January 06, 2015 5:32:00 PM

Dear Mr. Shen,

Thank you for your email and apologies for the delayed response.

The protocol itself appears to be written as a summary of other documents (methods, results, etc.). Because it is not the original method that was used to conduct the study, certain details are left out that would otherwise lend clarity to how the testing was performed. We recommend that you provide the original methods and accompanying complete test report for your antibacterial testing.

With regards to describing the sample groups, you refer to them alternately as “Test Group, Blank Group, and Control Group”, along with “first set,” “second set”, and “third set”. This is partially a side effect of the previously discussed issue, in which a summary is provided in story form instead of the original methods and protocols that were used. It may be helpful for you to examine other performance test reports as a guide. Consider employing tables and lists as needed to organize your test groups and clarify which samples were tested, how long they were tested for, which steps were performed for which samples, etc.

Please let me know if you have any other questions.

Sincerely,

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Cyshen@aol.com [mailto:Cyshen@aol.com]
Sent: Monday, January 05, 2015 8:18 AM
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 is on Hold Pending Your Response

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Charles Shen

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> U.S. Food and Drug Administration
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> 10903 New Hampshire Avenue
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> Please refer to the eCopy guidance at
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: cyshen@aol.com
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 is on Hold Pending Your Response
Date: Thursday, October 02, 2014 10:25:46 AM

Dear Mr Yang:

Thank you very much for providing deficiency letter on K141619/S001. We will be working very carefully to address all your comments.

Just have one question: In your comment 5(d) and 5(e), you mentioned that test method "AATCC-100 is not recoginized by FDA". Do I understand correctly that the statement means AATCC-100 is not on the list of FDA recognized standards. However, in the past AATCC 100 has been used in the evaluation of antibacterial dressings (including our predicate device), and the data generated can continue be used to establish the effacacy of antibacterial dressing, as long as the data and conclusion are scientifically justified.

Do I understand it correctly?

Thank you for your kind regards

Charles

-----Original Message-----
From: Peter Yang <peter.yang@fda.hhs.gov>
To: cyshen <cyshen@aol.com>
Cc: Peter Yang <peter.yang@fda.hhs.gov>
Sent: Fri, Sep 19, 2014 3:27 pm
Subject: K141619/S001 is on Hold Pending Your Response

September 19, 2014
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Please submit your response, referencing the submission number K141619/S001 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "cyshen@aol.com"
Cc: K141619@docs.fda.gov
Subject: RE: K141619/S001 is on Hold Pending Your Response
Date: Thursday, October 02, 2014 3:31:00 PM

Dear Mr. Shen,

Thanks for your email. Yes, AATCC-100 is not an FDA recognized standard. You may use the standard as a basis or foundation for evaluating the silver's preservative antibacterial effect within the dressing. However, you should clearly describe how you followed the test method, how you deviated from the test method, and why you made the particular choices you made, so that we can understand the methodology behind how the test was conducted. We will use your method and justification to evaluate whether the data substantiate your antibacterial claims and how your data compares to your predicate device's performance data.

Please let me know if you have any other questions.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: cyshen@aol.com [mailto:cyshen@aol.com]
Sent: Thursday, October 02, 2014 10:26 AM
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 is on Hold Pending Your Response

Dear Mr Yang:

Thank you very much for providing deficiency letter on K141619/S001. We will be working very carefully to address all your comments.

Just have one question: In your comment 5(d) and 5(e), you mentioned that test method "AATCC-100 is not recoginized by FDA". Do I understand correctly that the statement means AATCC-100 is not on the list of FDA recognized standards. However, in the past AATCC 100 has been used in the evaluation of antibacterial dressings (including our predicate device), and the data generated can continue be used to establish the effacacy of antibacterial dressing, as long as the data and conclusion are scientifically justified.

Do I understand it correctly?

Thank you for your kind regards

Charles

-----Original Message-----
From: Peter Yang <peter.yang@fda.hhs.gov>
To: cyshen <cyshen@aol.com>
Cc: Peter Yang <peter.yang@fda.hhs.gov>
Sent: Fri, Sep 19, 2014 3:27 pm
Subject: K141619/S001 is on Hold Pending Your Response

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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September 19, 2014
We have reviewed your submission K141619/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.
Please submit your response, referencing the submission number K141619/S001 to:
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Please refer to the eCopy guidance at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
for current information on the number of copies and the format (paper versus eCopy) you must submit.
Your response is due within 180 days from the date of this request, which is March 18, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.
You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.
If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.
Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

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From: Dang, Jiyoung M
To: Yang, Peter (CDRH); Yoon, Diana
Subject: RE: K141619/S001 review complete [AINN]
Date: Friday, September 19, 2014 6:52:47 AM

Hi Peter and Diana,

I've signed and uploaded the memo for this 510k into docman

Peter – I have some suggestions for you to consider below. Once you have the final set of deficiencies, please upload a separate file listing only the deficiencies into docman and let Diana know so that she can log out this file.

Diana – the SI due date falls on Sunday, so it is effectively due today.

Thanks,
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FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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Thanks,
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Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
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To: Yoon, Diana
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Date: Friday, September 19, 2014 11:01:00 AM

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From: Yoon, Diana
To: Yang, Peter (CDRH)
Subject: RE: K141619/S001 review complete [AINN]
Date: Friday, September 19, 2014 12:35:00 PM

Hi Peter,

I looked over your deficiencies. I have a few comments/edits so when you get a chance please stop by my office.

Thanks,
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Diana M. Yoon, PhD | Biomedical Engineer
Center for Devices and Radiological Health **|** Office of Device Evaluation **|** Division of Surgical Devices **|** Plastic and Reconstructive Surgery Devices Branch 2
U.S. Food and Drug Administration
10903 New Hampshire Avenue **|** WO66 - Room G449 | Silver Spring, MD 20993
301-796-7066 **|** diana.yoon@fda.hhs.gov
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Date: Friday, September 19, 2014 1:47:00 PM

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301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Dang, Jiyoung M
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 review complete [AINN]
Date: Thursday, September 18, 2014 6:14:52 PM

You can log out with ai without having to close out consult

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=400&D=480&B=485&E=&S=E

Sent from my Blackberry

From: Yang, Peter (CDRH)
Sent: Thursday, September 18, 2014 06:00 PM
To: Dang, Jiyoung M
Cc: Yoon, Diana
Subject: K141619/S001 review complete [AINN]

Hi Jiyoung,

I've completed the review of K141619, Huizhou Foryou Medical Devices' Luofucon Silver Foam Dressing. I recommend AI (AINN). Please find the memo on DocMan, along with the microbiology consult from Karoll Cortez of INCB.

I have not yet logged out in CTS, but that is because I'm waiting on the consult to be signed; it is not signed by her branch chief yet. Once that is done, I will update it accordingly.

Today, Thursday, September 18, is Day 57 – effectively it is due tomorrow, Friday, September 19.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, Plastic and Reconstructive Surgery Devices Branch II
Division of Surgical Devices
FDA/CDRH/ODE
White Oak Building #66, Room G435
10903 New Hampshire Avenue

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Silver Spring, MD 20993
301-796-5650 (main) 301-796-6477 (direct line)
Email: peter.yang@fda.hhs.gov
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From: Yang, Peter (CDRH)
To: Dang, Jiyoung M
Subject: RE: K141619/S001 review complete [AINN]
Date: Thursday, September 18, 2014 10:28:00 PM

Logged out, thanks!

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Dang, Jiyoung M
Sent: Thursday, September 18, 2014 6:15 PM
To: Yang, Peter (CDRH)
Subject: Re: K141619/S001 review complete [AINN]

You can log out with ai without having to close out consult

Jiyoung M. Dang, Ph.D.
Branch Chief, Plastic and Reconstructive Surgery Branch II
FDA | CDRH | Office of Device Evaluation | Division of Surgical Devices

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: cyshen
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619/S002 is on Hold Pending Your Response
Date: Monday, February 09, 2015 10:22:43 AM

Dear Dr Yang

Next week works for us. Thank you very much

Charles

发自我的 iPhone

在 Feb 9, 2015,10:10 AM,Yang, Peter (CDRH) <Peter.Yang@fda.hhs.gov> 写道:

> Dear Charles,
>
> Thanks for your email and for your questions. We will take a look at your questions and provide you with an answer by early next week. Let me know if that works for you.
>
> Thanks,
>
> Peter J. Yang, Ph.D.
> Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2
>
> 301-796-6477
> Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.
>
> ---
>
> **From:** Cyshen@aol.com [mailto:Cyshen@aol.com]
> **Sent:** Monday, February 09, 2015 8:01 AM
> **To:** Yang, Peter (CDRH)
> **Subject:** Re: K141619/S002 is on Hold Pending Your Response
>
> Dear Dr Yang:
>
> Thank you very much for your second deficiency letter on K141619/S002. We are reviewing your comments and working on addressing all issues carefully. We have a few questions, can you please kindly enlighten us?
>
> **Regarding your comment #2:**
>
> The temperature we choose was 45 C, which means that the nutrient agar will be below 45℃ before mixed with bacteria. This is the same temperature recommended by USP <61> "microbiological examination of nonsterile product: microbial enumeration test" for Pour-plate-Method. Do you think this temperarure will still lyse, inactivate, and/or hinder bacterial growth?
>
> Secondly, in antibacterial effectiveness test, test article will be neutralized by 100 mL D/E broth finally. From USP <61>, 1 mL D/E broth is recommended for Pour-Plate-Method while 0.1 mL for Surface-Spread-Method. If there were 500 bacteria in 100 mL D/E broth, 5 bacterial colony may be counted by using Pour-Plate-Method, but maybe none bacterial colony would be counted by Surface-Spread-Method.
>
> So does this mean Pour-Plate-Method is more precision than Surface-Spread-Method (which you recommended in the deficiency letter)?
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> We will certainly do whatever you recommend for us. Could you please kindly confirm if FDA could accept

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

our current practice or still like us to take the alternative approach?

Regarding your comment #1:

We will take 1a approach. The protaocol is attached. Can you please kindly review and advise if our methodology is accepatable by FDA?

Also if testing one lot is acceptable for this specific experiment? Because the historical samples were not tested by this new approach, we may not able to provide results on stability samples using this new method, is that okay?

Regarding your comment #4:

These results and test reports were provided in S002. Please see the following three documents:
014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Please see following sections in all three document: 5.2.8: Seal Strength, 5.2.9: Dye Penetration; 5.2.10: Sterility

All three reports are attached for your examination

Look forward to your kind response and thank you very much for your help

Charles shen

In a message dated 2/2/2015 7:17:52 P.M. Eastern Standard Time, peter.yang@fda.hhs.gov writes:

> February 2, 2015
>
> We have reviewed your submission K141619/S002 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.
>
> Please submit your response, referencing the submission number K141619/S002 to:
>
> U.S. Food and Drug Administration
> Center for Devices and Radiological Health
> Document Control Center - WO66-G609
> 10903 New Hampshire Avenue
> Silver Spring, MD 20993-0002
>
> Please refer to the eCopy guidance at
> http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
> for current information on the number of copies and the format (paper versus eCopy) you must submit.
>
> Your response is due within 180 days from the date of this request, which is August 1, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.
>
> You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.
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> If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "cyshen"
Cc: K141619@docs.fda.gov
Subject: RE: K141619/S002 is on Hold Pending Your Response
Date: Wednesday, February 25, 2015 6:38:00 PM

Dear Mr. Shen,

Thank you for your questions and sincere apologies for our delay. Our responses are below.

We believe that pour plating, as enumerated in USP <61>, is not appropriate for your testing for the following reasons:

a. FDA/CDRH does not recognize a standard for the purposes of antibacterial or antimicrobial testing.
b. The combination of molten agar adds extra stress (heat) to the bacteria. Although a temperature of 45°C may not visibly kill the entire bacterial culture, it will likely affect bacterial growth in different ways that are organism dependent.
c. Culturing bacteria both within agar and on the surface leads to colonies that grow differently depending on their location. Bacteria growing within agar are additionally exposed to an oxygen deficient environment and are therefore placed under additional stress. Five of the bacteria tested (including *E. faecalis*, *E. coli*, *K. pneumoniae*, *S. aureus*, and *S. pyogenes*) are considered "facultative anaerobes," meaning that they can survive in the absence of oxygen (although not preferred). However, one of the organisms you have tested is *Pseudomonas aeruginosa*, an obligate aerobe, and will not appropriately grow within the agar.
d. Aerobic bacteria near and on the surface will have larger colonies than ones embedded within the agar. This results in difficulty and subjectivity during colony counting, especially if the plate is being divided into quadrants to expedite counting.
e. Pour plating is difficult to provide an even distribution of bacteria throughout the plate, which may lead to additional problems in colony counting of more concentrated areas of growth.
f. There is a higher risk of contamination:
    i. By not having a consistent colony size and morphology to count, pour plating may lead to missing the presence of mixed colonies that result from contamination.
    ii. By mixing the molten agar/media directly with bacteria, one may miss the presence of contaminating organisms. Incubating an extra plate without bacteria as a contamination check does not eliminate this concern, as each plate is individually subject to contamination.
g. During spread plating, all plates are prepared with the same stock and concentration of media and poured at one time, then confirmed to be free from contamination prior to use. While in pour platting (especially during a time-study), multiple batches of media will need to be made on different days (for each time point), introducing more experimental variation that could impact bacterial growth and overall log reduction calculations.

In summary, we believe that spread plating is an improvement in the scientific methodology underlying the practical aspects of colony counting. Spread plating is a method that has less stress on the organisms, less variables that will impact bacterial growth, is easier to control even spreading of the organism, is less subjective when performing colony counting, and has more control when avoiding contamination. If you choose to continue using pour plating, please provide an adequate scientific justification for why pour plating is preferred to spread plating.

Regardless of your method, we recommend that you provide the raw colony counting data (i.e. number of CFUs counted on each plate) in your response so that we may confirm that you have sufficient colonies before and after to establish a 4 log reduction.

With regards to your comments regarding D/E solution, we believe you may have misinterpreted the addition of neutralizing solution. We understand that different amounts of D/E solution should be added *in addition* to the volume of organism to be plated. Thus, the organism concentration would be the same. We recommend that the organism should be diluted such that the final plate count is between 30-300 CFUs. If you have additional questions regarding this issue, please send your neutralization protocol and we can informally review your provided protocol. You may also wish to submit a Pre-Submission for formal communication with us.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We believe your protocol as provided (regarding approach #1a) is appropriate. In this instance, we will accept the preservative effectiveness results for one aged lot given that the testing you provide adequately substantiates preservative effectiveness and given the other data you have provided concerning silver release from your device.

Finally, we will review the packaging test reports you provided.

If you have any questions, please email me. In this instance we believe communicating interactively is most effective; however, in most cases, we would prefer that these questions be submitted as part of a Pre-Submission.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: cyshen [mailto:cyshen@aol.com]
Sent: Monday, February 09, 2015 10:22 AM
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619/S002 is on Hold Pending Your Response

Dear Dr Yang

Next week works for us. Thank you very much

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From: Cyshen@aol.com
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619/S002 is on Hold Pending Your Response
Date: Tuesday, March 10, 2015 8:41:36 AM

Dear Peter

Thank you very much for your detailed explanation. We will perform the anitibacterial test exactly following your recommendations

Just wandering if you have finished reviewing packaging test report mentioned in your email below? Or will you review it as part of S003?

One additional question about labeling: While we state the antibacterial perservative effectiveness of three days, can we also claim additional days for sole use as wound dressing, based on the estimated daily wound fluid and dressing's absorption capability?

Thanks

Charles

In a message dated 2/25/2015 6:38:19 P.M. Eastern Standard Time, Peter.Yang@fda.hhs.gov writes:

> Dear Mr. Shen,
>
> Thank you for your questions and sincere apologies for our delay. Our responses are below.
>
> We believe that pour plating, as enumerated in USP <61>, is not appropriate for your testing for the following reasons:
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> a. FDA/CDRH does not recognize a standard for the purposes of antibacterial or antimicrobial testing.
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Peter

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Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "Cyshen@aol.com"
Cc: K141619@docs.fda.gov
Subject: RE: K141619/S002 is on Hold Pending Your Response
Date: Thursday, March 12, 2015 3:10:00 PM

Dear Charles,

We will review your packaging testing as part of Supplement 003.

We do not believe that stating additional time for use as a wound dressing beyond what is noted by your performance testing to be clinically appropriate. The function of silver in your dressing, as with other preservatives, is to reduce bacterial contamination of the dressing. The statement that your device can be used beyond its preservative effectiveness implies that you believe bacterial contamination after three days is acceptable. However, the risk of dressing contamination rises as the dressing remains on a wound for a longer period of time. A dressing that has absorbed more fluid may also have an increased risk of contamination as there is more available exudate for microbial colonization. Therefore, labeling that your device can be used beyond the length of time of preservative effectiveness may not be clinically justified.

If you still wish to add this claim, please provide an adequate justification for why using your device beyond three days is clinically appropriate. Such justification may include appropriate scientific literature as well as pre-clinical or clinical performance testing.

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Cyshen@aol.com [mailto:Cyshen@aol.com]
Sent: Tuesday, March 10, 2015 8:42 AM
To: Yang, Peter (CDRH)
Cc: K141619@docs.fda.gov
Subject: Re: K141619/S002 is on Hold Pending Your Response

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> a. FDA/CDRH does not recognize a standard for the purposes of antibacterial or antimicrobial testing.
> b. The combination of molten agar adds extra stress (heat) to the bacteria. Although a temperature of 45°C may not visibly kill the entire bacterial culture, it will likely affect bacterial growth in different ways that are organism dependent.
> c. Culturing bacteria both within agar and on the surface leads to colonies that grow differently depending on their location. Bacteria growing within agar are additionally exposed to an oxygen deficient environment and are therefore placed under additional stress. Five of the bacteria tested (including *E. faecalis*, *E. coli*, *K. pneumoniae*, *S. aureus*, and *S. pyogenes*) are considered "facultative anaerobes," meaning that they can survive in the absence of oxygen (although not preferred). However, one of the organisms you have tested is *Pseudomonas aeruginosa*, an obligate aerobe, and will not appropriately grow within the agar.
> d. Aerobic bacteria near and on the surface will have larger colonies than ones embedded within the agar. This results in difficulty and subjectivity during colony counting, especially if the plate is being divided into quadrants to expedite counting.
> e. Pour plating is difficult to provide an even distribution of bacteria throughout the plate, which may lead to additional problems in colony counting of more concentrated areas of growth.
> f. There is a higher risk of contamination:
>
> i. By not having a consistent colony size and morphology to count, pour plating may lead to missing the presence of mixed colonies that result from contamination.
> ii. By mixing the molten agar/media directly with bacteria, one may miss the presence of contaminating organisms. Incubating an extra plate without bacteria as a contamination check does not eliminate this concern, as each plate is individually subject to contamination.
>
> g. During spread plating, all plates are prepared with the same stock and concentration of media and poured at one time, then confirmed to be free from contamination

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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prior to use. While in pour platting (especially during a time-study), multiple batches of media will need to be made on different days (for each time point), introducing more experimental variation that could impact bacterial growth and overall log reduction calculations.

In summary, we believe that spread plating is an improvement in the scientific methodology underlying the practical aspects of colony counting. Spread plating is a method that has less stress on the organisms, less variables that will impact bacterial growth, is easier to control even spreading of the organism, is less subjective when performing colony counting, and has more control when avoiding contamination. If you choose to continue using pour plating, please provide an adequate scientific justification for why pour plating is preferred to spread plating.

Regardless of your method, we recommend that you provide the raw colony counting data (i.e. number of CFUs counted on each plate) in your response so that we may confirm that you have sufficient colonies before and after to establish a 4 log reduction.

With regards to your comments regarding D/E solution, we believe you may have misinterpreted the addition of neutralizing solution. We understand that different amounts of D/E solution should be added *in addition* to the volume of organism to be plated. Thus, the organism concentration would be the same. We recommend that the organism should be diluted such that the final plate count is between 30-300 CFUs. If you have additional questions regarding this issue, please send your neutralization protocol and we can informally review your provided protocol. You may also wish to submit a Pre-Submission for formal communication with us.

We believe your protocol as provided (regarding approach #1a) is appropriate. In this instance, we will accept the preservative effectiveness results for one aged lot given that the testing you provide adequately substantiates preservative effectiveness and given the other data you have provided concerning silver release from your device.

Finally, we will review the packaging test reports you provided.

If you have any questions, please email me. In this instance we believe communicating interactively is most effective; however, in most cases, we would prefer that these questions be submitted as part of a Pre-Submission.

Thanks,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Cyshen@aol.com
To: Yang, Peter (CDRH)
Subject: Re: K141619/S002 is on Hold Pending Your Response
Date: Monday, February 09, 2015 8:01:18 AM
Attachments: 016_RE~1.ZIP

Dear Dr Yang:

Thank you very much for your second deficiency letter on K141619/S002. We are reviewing your comments and working on addressing all issues carefully. We have a few questions, can you please kindly enlighten us?

Regarding your comment #2:

The temperature we choose was 45 C, which means that the nutrient agar will be below 45℃ before mixed with bacteria. This is the same temperature recommended by USP <61> "microbiological examination of nonsterile product: microbial enumeration test" for Pour-plate-Method. Do you think this temperarure will still lyse, inactivate, and/or hinder bacterial growth?

Secondly, in antibacterial effectiveness test, test article will be neutralized by 100 mL D/E broth finally. From USP <61>, 1 mL D/E broth is recommended for Pour-Plate-Method while 0.1 mL for Surface-Spread-Method. If there were 500 bacteria in 100 mL D/E broth, 5 bacterial colony may be counted by using Pour-Plate-Method, but maybe none bacterial colony would be counted by Surface-Spread-Method.

So does this mean Pour-Plate-Method is more precision than Surface-Spread-Method (which you recommended in the deficiency letter)?

We will certainly do whatever you recommend for us. Could you please kindly confirm if FDA could accept our current practice or still like us to take the alternative approach?

Regarding your comment #1:

We will take 1a approach. The protaocol is attached. Can you please kindly review and advise if our methodology is accepatable by FDA?

Also if testing one lot is acceptable for this specific experiment? Because the historical samples were not tested by this new approach, we may not able to provide results on stability samples using this new method, is that okay?

Regarding your comment #4:

These results and test reports were provided in S002. Please see the following three documents:
014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Please see following sections in all three document: 5.2.8: Seal Strength, 5.2.9: Dye Penetration; 5.2.10: Sterility

All three reports are attached for your examination

Look forward to your kind response and thank you very much for your help

Charles shen

In a message dated 2/2/2015 7:17:52 P.M. Eastern Standard Time, peter.yang@fda.hhs.gov writes:

> February 2, 2015
>
> We have reviewed your submission K141619/S002 and have determined that additional information is

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K141619/S002 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is August 1, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: "Cyshen@aol.com"
Cc: K141619@docs.fda.gov
Subject: RE: K141619/S002 is on Hold Pending Your Response
Date: Monday, February 09, 2015 10:10:00 AM

Dear Charles,

Thanks for your email and for your questions. We will take a look at your questions and provide you with an answer by early next week. Let me know if that works for you.

Thanks,

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Cyshen@aol.com [mailto:Cyshen@aol.com]
Sent: Monday, February 09, 2015 8:01 AM
To: Yang, Peter (CDRH)
Subject: Re: K141619/S002 is on Hold Pending Your Response

Dear Dr Yang:

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015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Please see following sections in all three document: 5.2.8: Seal Strength, 5.2.9: Dye Penetration; 5.2.10: Sterility

All three reports are attached for your examination

Look forward to your kind response and thank you very much for your help

Charles shen

In a message dated 2/2/2015 7:17:52 P.M. Eastern Standard Time, peter.yang@fda.hhs.gov writes:

> February 2, 2015
>
> We have reviewed your submission K141619/S002 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.
>
> Please submit your response, referencing the submission number K141619/S002 to:
>
> U.S. Food and Drug Administration
> Center for Devices and Radiological Health
> Document Control Center - WO66-G609
> 10903 New Hampshire Avenue
> Silver Spring, MD 20993-0002
>
> Please refer to the eCopy guidance at
> http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
> for current information on the number of copies and the format (paper versus eCopy) you must submit.
>
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>
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>
> If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.
>
> Should you have questions about this email, you may contact Peter Yang, the lead reviewer assigned to your submission.
>
> *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

From: Yang, Peter (CDRH)
To: Claverie, Elizabeth F
Cc: Panguluri, Ramesh K
Subject: RE: k141619-consults
Date: Friday, August 08, 2014 12:10:00 PM

Hi Liz,

Done, thanks!

Sincerely,
Peter

Peter J. Yang, Ph.D.
Biomedical Engineer, FDA/CDRH/ODE/DSD/PRSB2

301-796-6477
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Claverie, Elizabeth F
Sent: Friday, August 08, 2014 11:47 AM
To: Yang, Peter (CDRH)
Cc: Panguluri, Ramesh K
Subject: k141619-consults
Importance: High

Hi Peter,
Kapil will mentor Karoll Cortez on this consult. Can you please place a bio risk consult in CTS for him as well.

Thank you,
Liz

Elizabeth F. Claverie-Williams, MS
Elizabeth F. Claverie-Williams, MS
CDR USPHS-CC, Microbiologist
Branch Chief, Infection Control Devices Branch
FDA/CDRH/ODE/DAGRID
10903 New Hampshire Ave.
White Oak, Bldg.66/Room 2508
Silver Spring, MD 20993
Office: 301-796-6298
Fax: 301-847-8109

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the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=435&E=&S=E

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 13: Proposed Labeling

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

Rx Only
Version: A/0

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure containing silver particles which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. The total maximum amount of silver partilces is 4ug/cm^3. The silver is present as a preservative to inhibit bacterial colonization within the dressing. LUOFUCON® Silver Foam Dressing has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.
The **Silver Foam Dressing with PU Backing** consists of silver foam and breathable polyurethane film for waterproof. The **Bordered Silver Foam Dressing** is silver foam on a PU/PET film or non-woven coated with acrylic adhesive and extends to act as a border adhesive to allow fixation without secondary dressing or fixation bandage.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers(venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns(1st and 2nd degree)

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

In Vitro Study Results:
This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria:

Proven Antibacterial Preservative Effectiveness

Bacterial	72 Hour Log Reduction
Staphylococcus aureus (ATCC 6538)	4 Log
Streptococcus pyogenes (ATCC 19615)	4 Log
Enterococcus faecalis (ATCC 29212)	4 Log
Escherlchia coli (ATCC 8739)	4 Log
Klesiella pneumonlae (ATCC 4352)	4 Log
Pseudomonas aeruginosa (ATCC 9027)	4 Log

Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Instructions for Use
1. Clean the wound with sterile saline water and dry the surrounding skin gently.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. The dressing should be left on the skin for no more than three days.

Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Specifications (Including 3mm and 5mm)

Foam or With PU Backing	PU or Non-woven Adhesive
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
125×100	150×150(100×100)
150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.2 Pouch Label

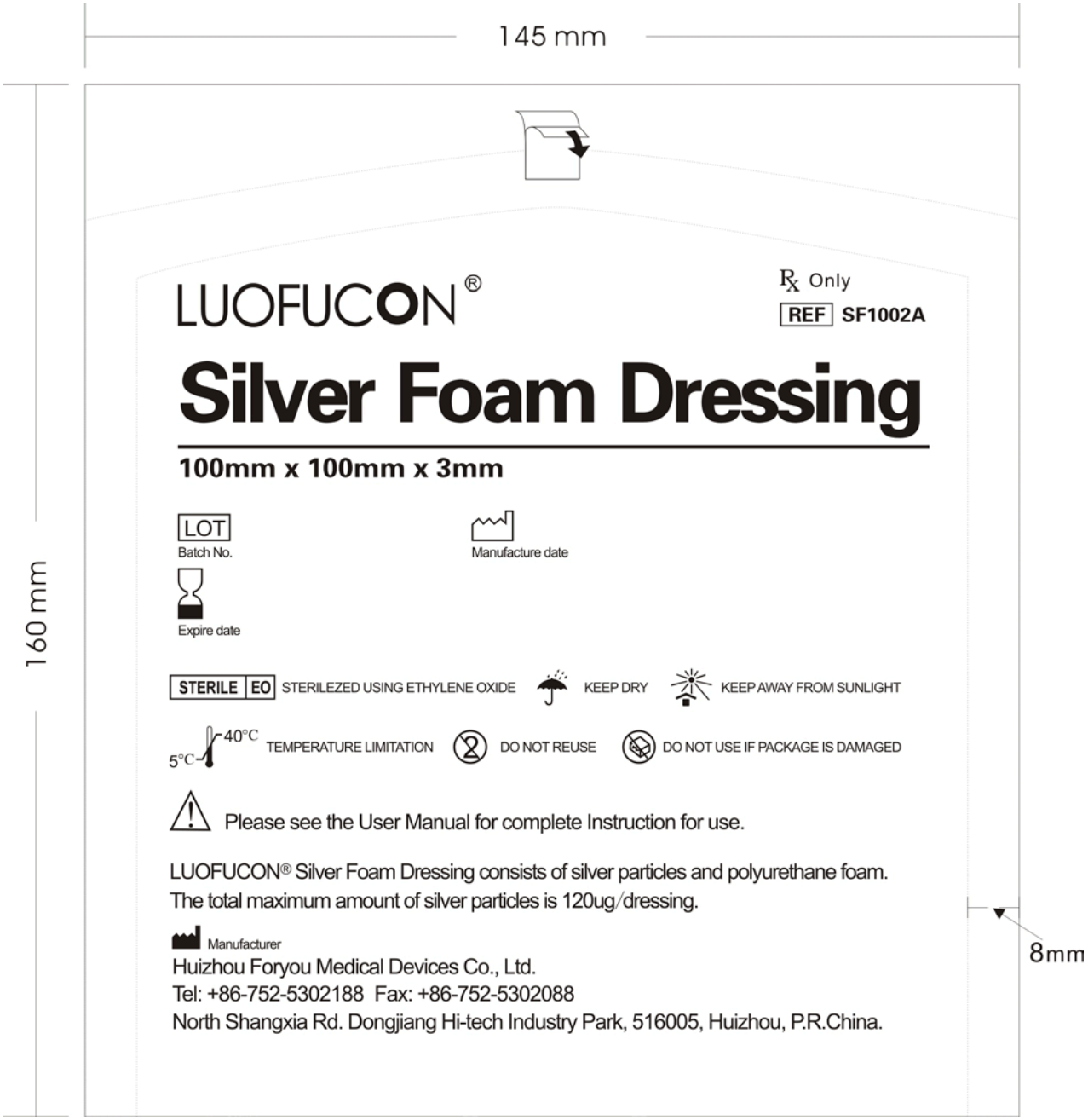
Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 13: Labeling: Prescription

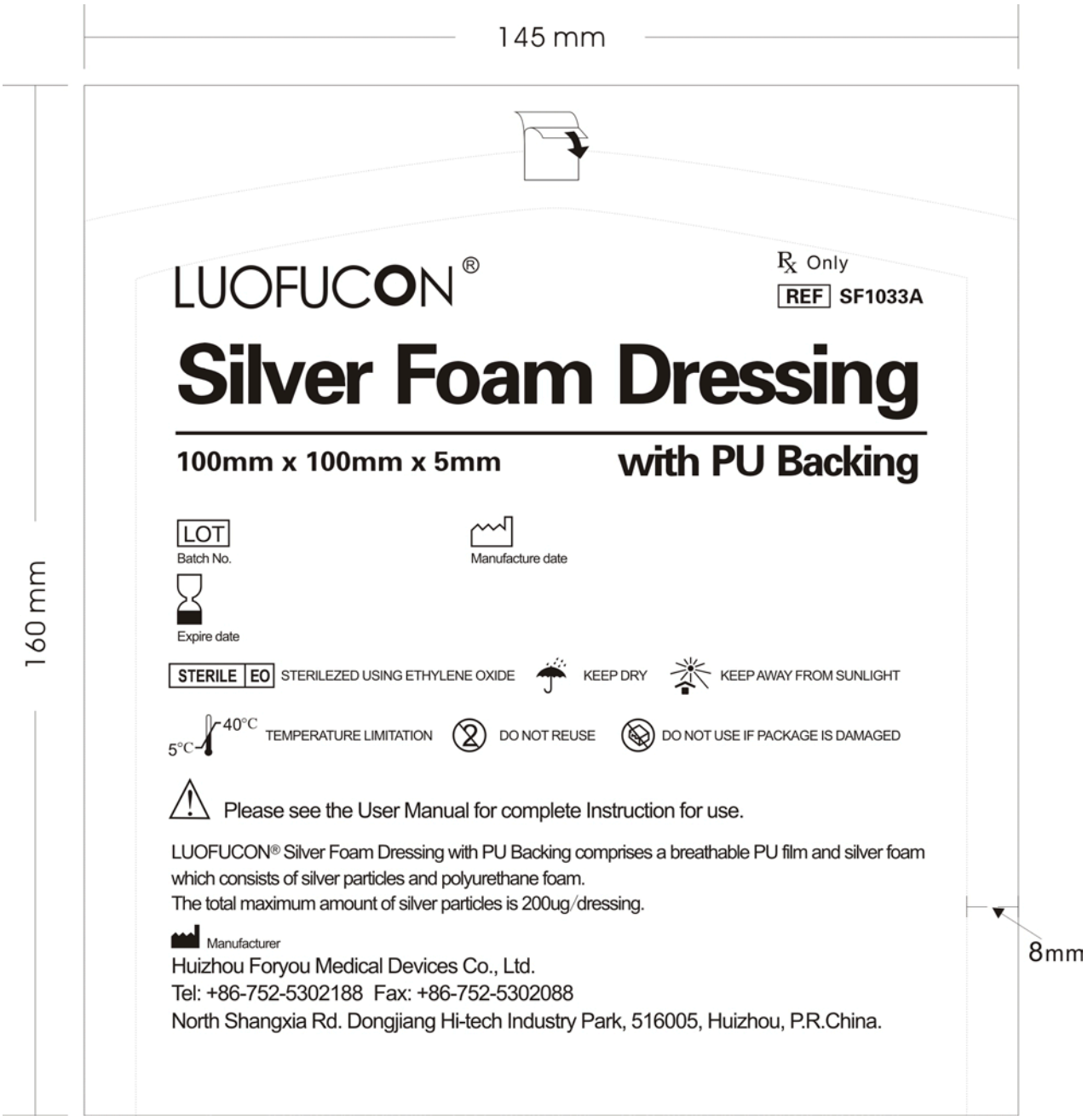
Variant 1:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

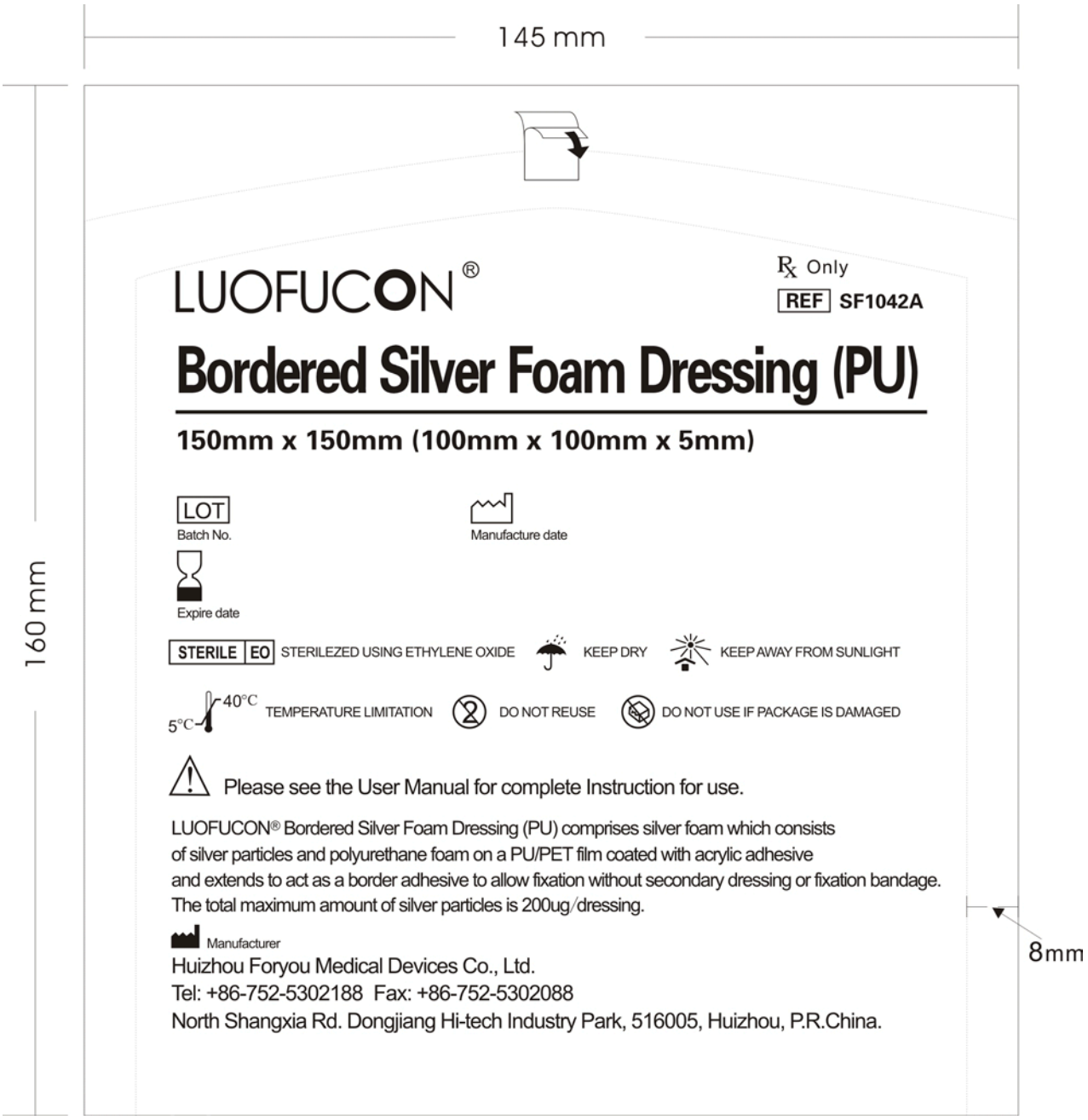
Variant 2:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

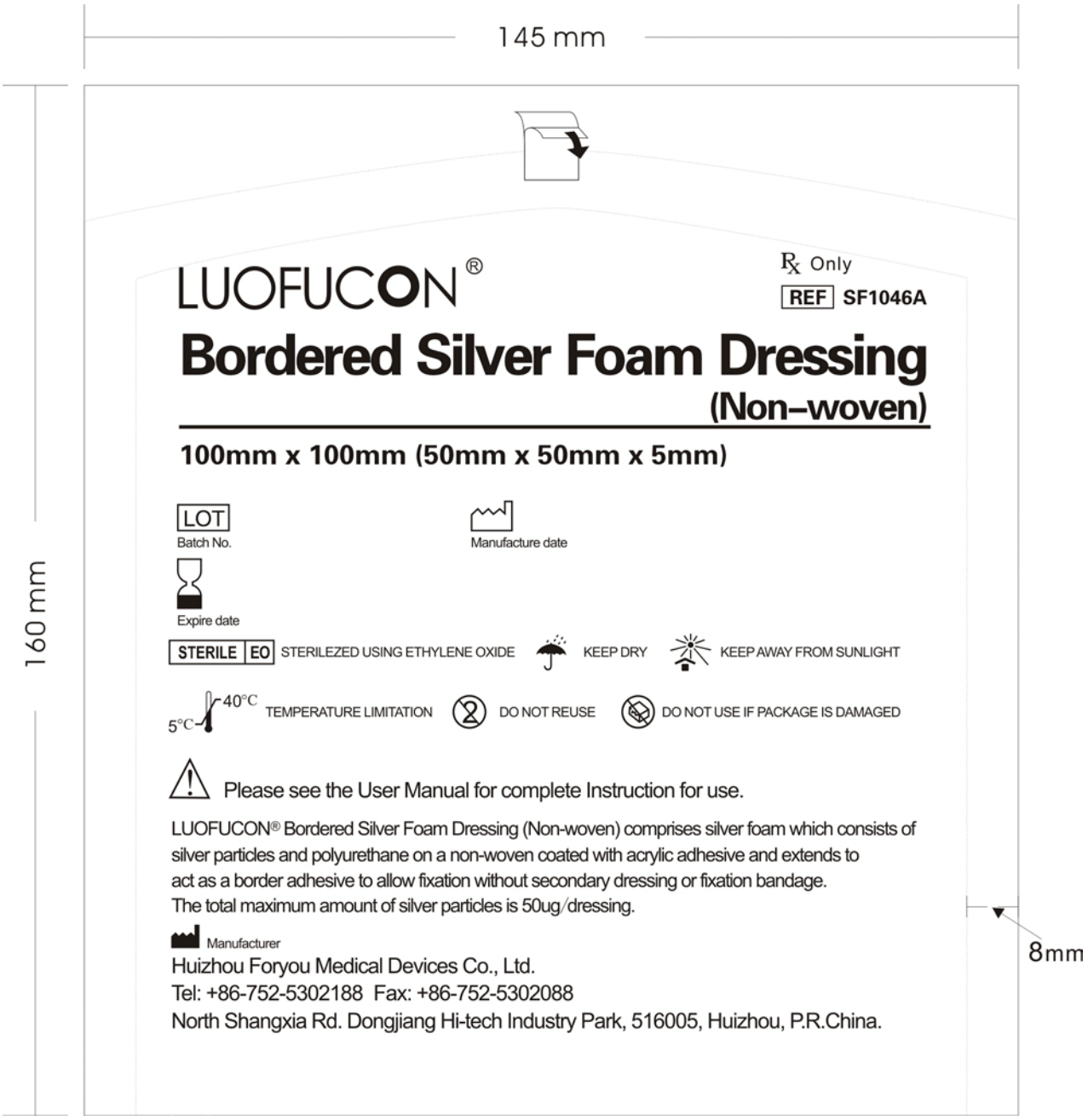
Variant 3:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Variant 4:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Variant 1



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 2:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 3:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 4:



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Section 13: Proposed Labeling

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150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.2 Pouch Label

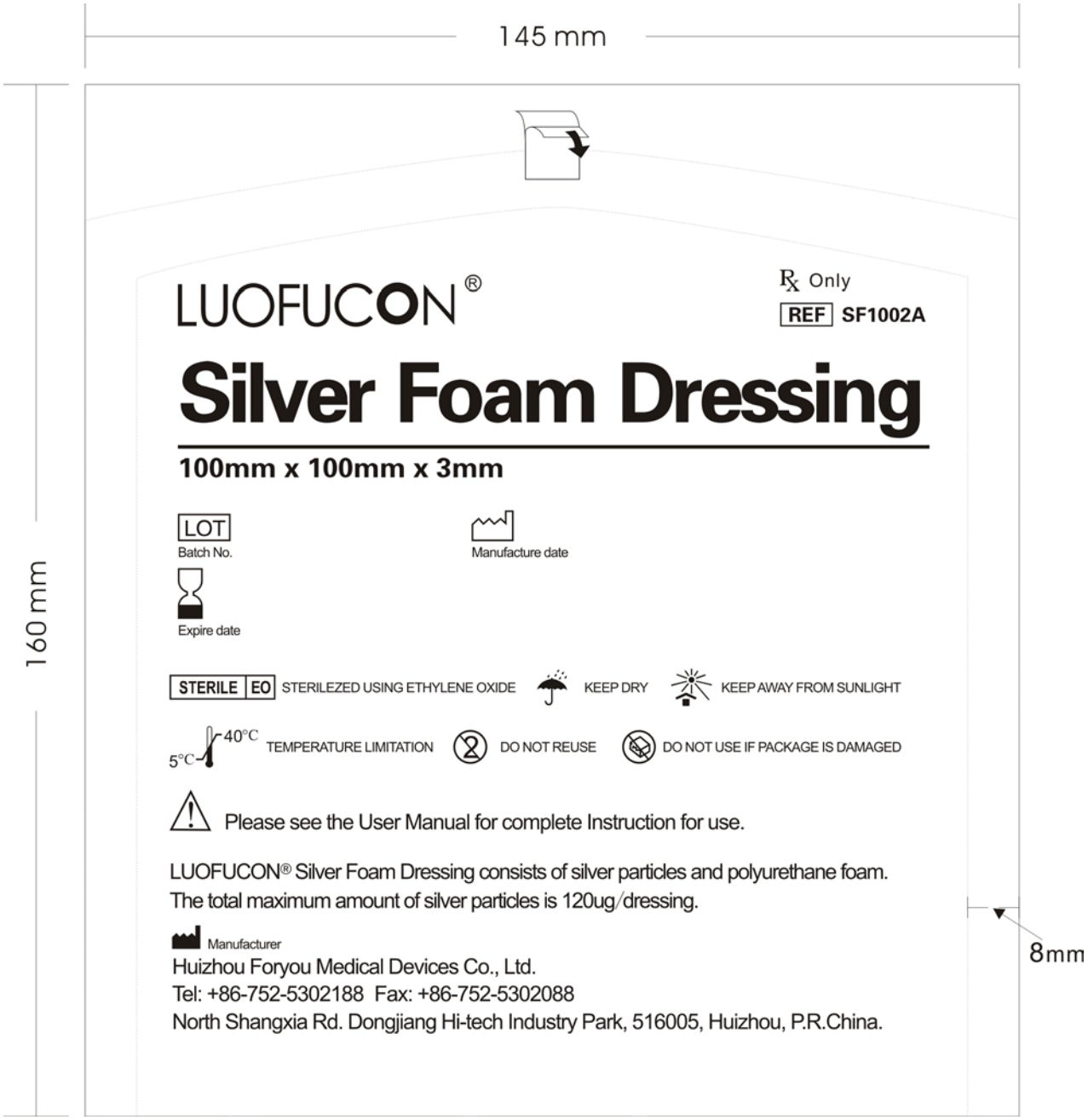
Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

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Section 13: Labeling: Prescription

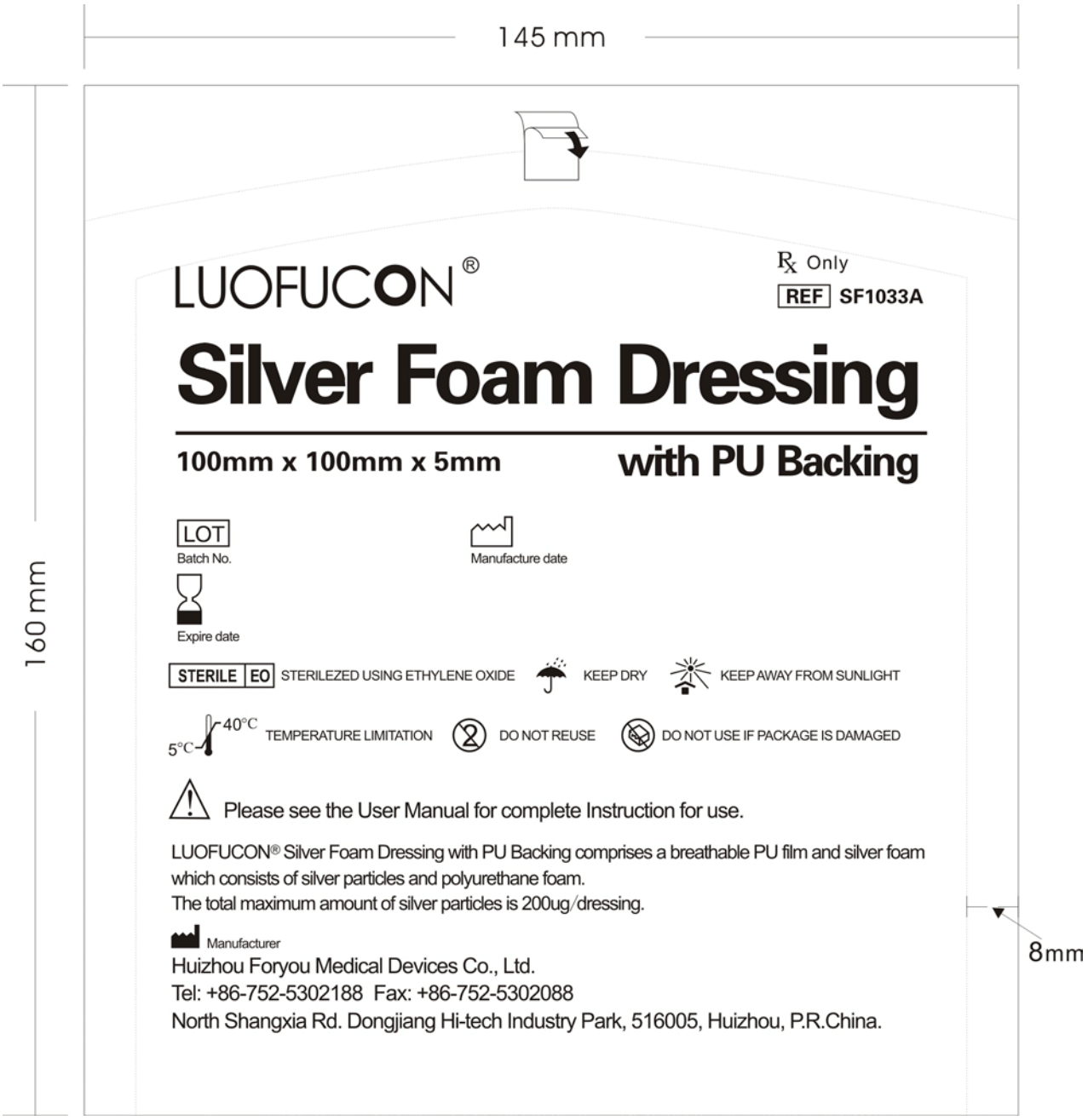
Variant 1:



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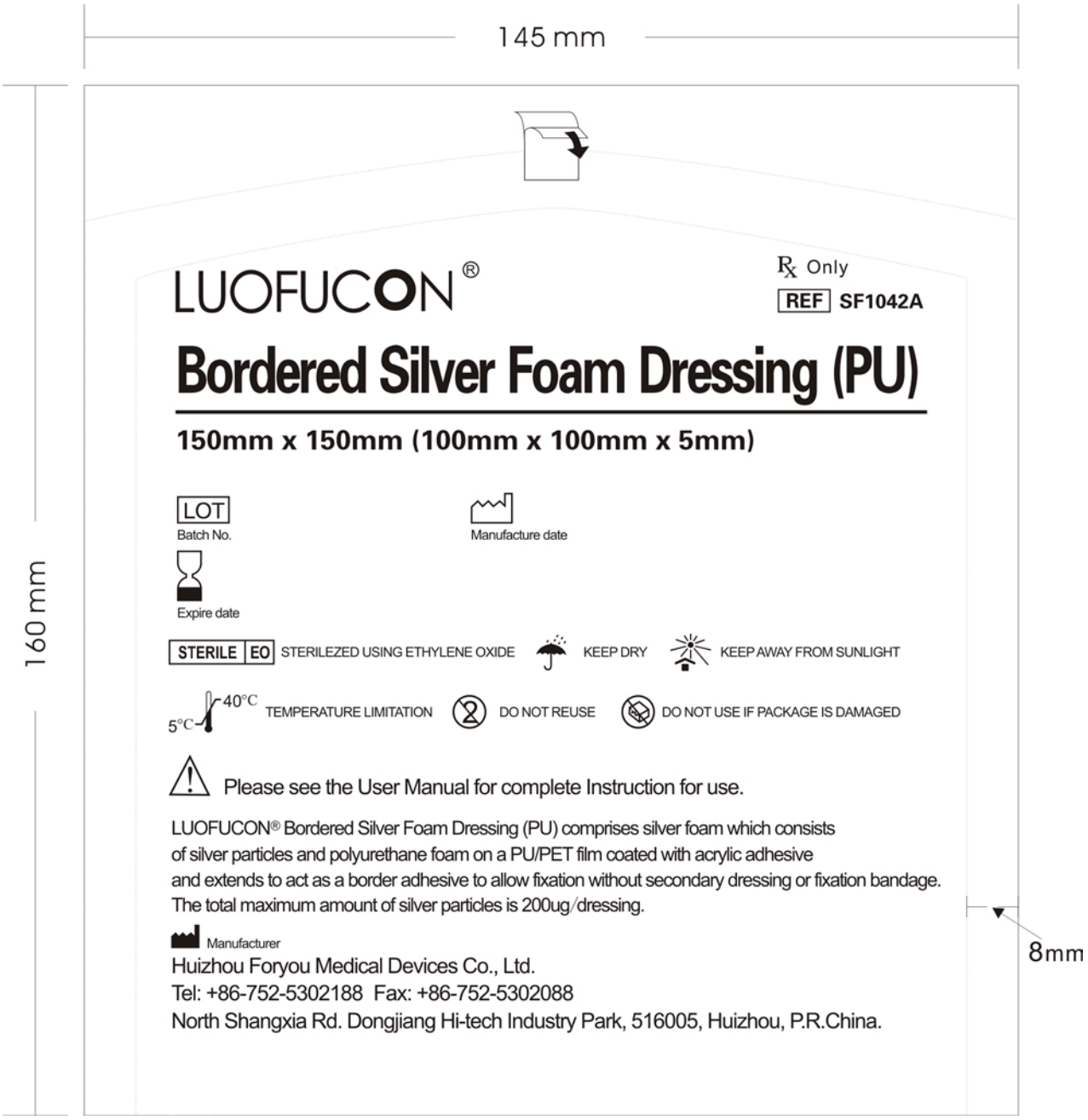
Variant 2:



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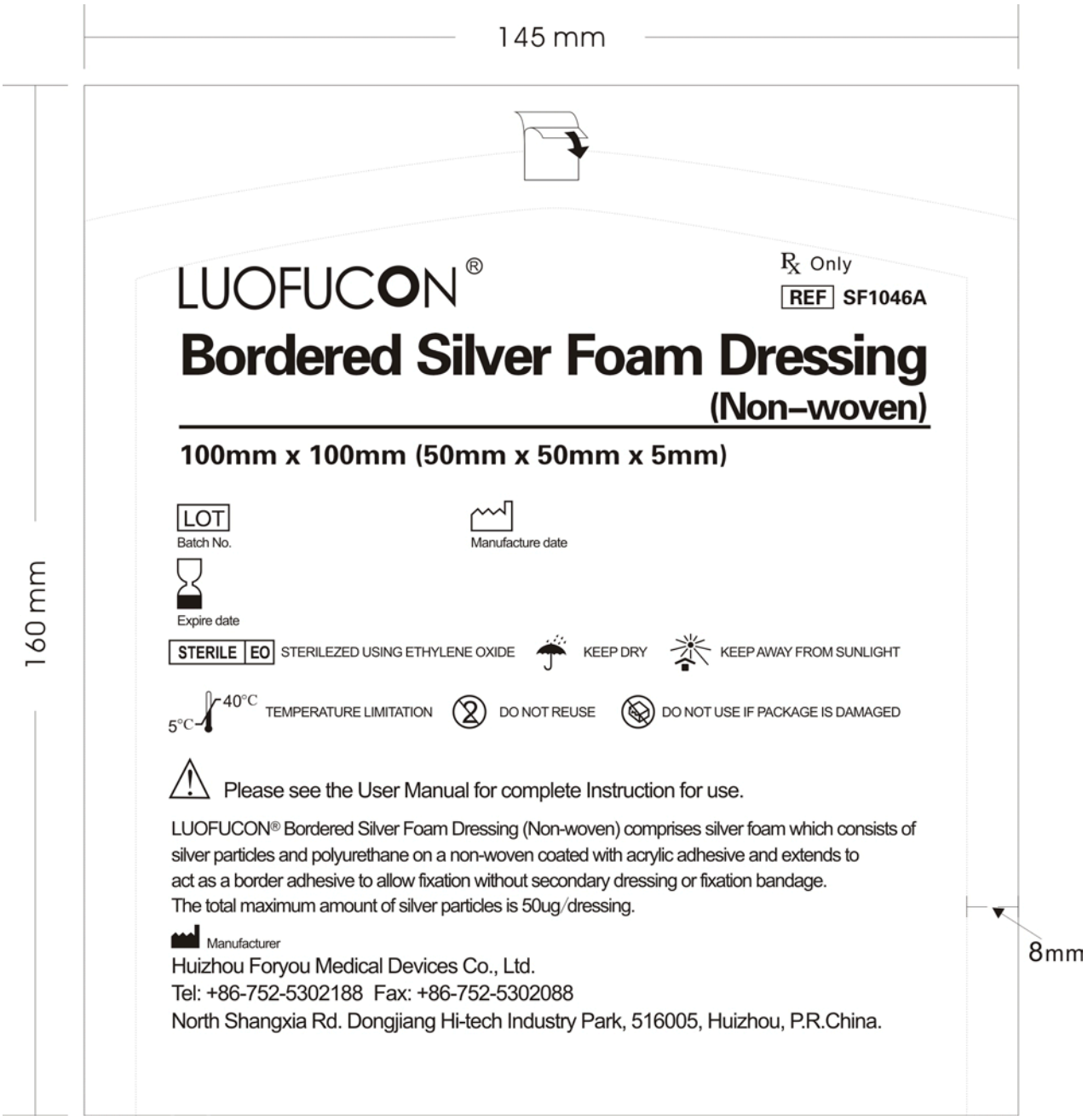
Variant 3:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 4:



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13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Variant 1



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Variant 2:



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Variant 3:



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Variant 4:



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510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Silver serves as a preservative against bacterial growth in the dressing material

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar

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materials, utilize same antibacterial mechanism, and have similar intended use.

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

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Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
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Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

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Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
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Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

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Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
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The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

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Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

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US Agent and Contact Person

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Email: cyshen@aol.com

Date of Summary: March 31, 2015

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial preservative agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	5-7 days

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

Huizhou Foryou Medical Devices Company, Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester Lane, Unit-B
Pennington, New Jersey 08534

Re: K141619
Trade/Device Name: Luofucon Silver Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 20, 2015
Received: March 24, 2015

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		X		X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Please clarify whether there are any prior submissions that are relevant to this device. If not, please state that there were no prior submissions.				
B. Device Description				
10)				

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.		X		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Please describe the function of the non-woven material layer in the fourth variant of your device.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		X		X
Comments? Please describe the thicknesses of the secondary layers in the second, third, and fourth variants of your device.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				

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(21 CFR 807.87 unless otherwise indicated)

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a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? The provided package labeling in p. 7 of Section 13 is too small to read and is thus illegible; please provide a zoomed-in depiction of the labeling.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	

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25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		X
Comments? Please identify the complete materials of construction for each of the variants of your device, including secondary layers and any adhesives that are used.				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(21 CFR 807.87 unless otherwise indicated)

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

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31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

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Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.07.01 11:49:37 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.07.01 16:12:19 -04'00'
Division Sign-Off (digital signature optional)*	David Krause -S 2014.07.01 16:18:50 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		X		X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Please clarify whether there are any prior submissions that are relevant to this device. If not, please state that there were no prior submissions.				
B. Device Description				
10)				

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.		X		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Please describe the function of the non-woven material layer in the fourth variant of your device.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		X		X
Comments? Please describe the thicknesses of the secondary layers in the second, third, and fourth variants of your device.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				

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a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? The provided package labeling in p. 7 of Section 13 is too small to read and is thus illegible; please provide a zoomed-in depiction of the labeling.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	

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25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		X
Comments? Please identify the complete materials of construction for each of the variants of your device, including secondary layers and any adhesives that are used.				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

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31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
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Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
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J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
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- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.07.01 11:49:37 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.07.01 16:12:19 -04'00'
Division Sign-Off (digital signature optional)*	David Krause -S 2014.07.01 16:18:50 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141619 Date Received by DCC: Jun 17, 2014

Lead Reviewer: Peter J. Yang, PhD

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

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A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
B. Device Description				
10)				

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments?				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments?				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	

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21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
× does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
× does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	×			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			×	
38) If literature is referenced in the submission, submission includes:			×	
39) For each completed nonclinical (i.e., animal) study conducted			×	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
× is not an in vitro diagnostic device.				

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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Peter Yang -S 2014.08.05 16:12:59 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.08.06 14:58:04 -04'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Food and Drug Administration

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510(k) Number *(if known)*
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- Pressure Sores
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- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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1-89

K141619

Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FDA CDRH DMC
JUN 17 2014
Received

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table of Content:

Section Number	Content
Section 1	Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2	CDRH Premarket Review Submission Cover Sheet
Section 3	510(k) Cover Letter
Section 4	Indications for Use Statement
Section 5	510(k) Summary
Section 6	Truthful and Accuracy Statement
Section 7	Class III Summary and Certification
Section 8	Financial Certification or Disclosure Statement
Section 9	Declarations of Conformity and Summary Reports
Section 10	Executive Summary
Section 11	Device Description
Section 12	Substantial Equivalence Discussion
Section 13	Proposed Labeling
Section 14	Sterilization and Shelf Life
Section 15	Biocompatibility
Section 16	Software
Section 17	Electromagnetic Compatibility and Electrical Safety
Section 18	Performance Testing – Bench
Section 19	Performance Testing – Animal
Section 20	Performance Testing – Clinical
Attachment 1	Form 3654s
Attachment 2	Form 3674
Appendix 1	Test Reports
Appendix 2	DMF Authorization Letters

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

HUIZHOU FORYOU MEDICAL DEVICES CO LTD
North Shangxia Road, Dongjiang Hi-tech Industry Park
HUIZHOU
China
Guangdong
516005
CN

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Jin Tuan Lin
2.1 E-MAIL ADDRESS
jtlin@foryougroup.com
2.2 TELEPHONE NUMBER (include Area code)
+86-0752 5302031
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
+86-0752 5302020

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
30-May-2014

Form FDA 3601 (07/2007)

"Close Window" Print Cover sheet

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/05/2014		

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*
HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD	3007735241
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	(086)0752-5302188
Street Address	**FAX Number *(including area code)***
No.1 Shangxia North Road, DONGJIANG HI-TECH INDUSTRIAL PARK	(086)0752-5302020

City	State / Province	ZIP/Postal Code	Country
Huizhou	Guangdong	516005	China

Contact Name	
Charles Shen	
Contact Title	**Contact E-mail Address**
Regulatory Correspondent	cyshen@aol.com

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	
MANTON BUSINESS AND TECHNOLOGY SERVICES	
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	001-608-217-9358
Street Address	**FAX Number *(including area code)***
853 Dorchester LN, Unit-B	001-425-930-2155

City	State / Province	ZIP Code	Country
New Milford	NJ	07646	USA

Contact Name	
Charles Shen	
Contact Title	**Contact E-mail Address**
N/A	cyshen@aol.com

PSC Publishing Services (301) 443-6740 EF

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K110062	MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFo	MediPurpose, Pte. Ltd
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Luofucon Silver Foam Dressing

	Trade or Proprietary or Model Name for This Device	Model Number
1	Luofucon Silver Foam Dressing	Various
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1		2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FRO

C.F.R. Section *(if applicable)*: N/A

Device Class

- [ ] Class I
- [ ] Class II
- [ ] Class III
- [x] Unclassified

Classification Panel

general & plastic surgery

Indications *(from labeling)*

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
Ulcers (venous, arterial, diabetic) Pressure Sores Donor Sites Surgical Incisions Surgical Excisions Burns (1st and 2nd degree)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: 3007735241

☒ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD	3007735241
Division Name *(if applicable)*	**Phone Number *(including area code)***
N/A	(086)0752-5302188
Street Address	**FAX Number *(including area code)***
No.1 Shangxia North Road, DONGJIANG HI-TECH INDUSTRIAL PARK	(086)0752-5302020

City	State / Province	ZIP Code	Country
Huizhou	Guangdong	516005	China

Contact Name	Contact Title	Contact E-mail Address
Charles Shen	Regulatory Correspondent	cyshen@aol.com

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
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Street Address	**FAX Number *(including area code)***

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Contact Name	Contact Title	Contact E-mail Address

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO-10993-5	ISO	Biological Evaluation of medical Devices. Part 5- Tests for in Vitro Cytotoxieity	2009	7/31/2009
2	ISO-10993-10	ISO	Biological Evaluation of medical Devices. Part 10- Tests for irritation and Delayed Type Hypersensitivity	2010	12/31/2010
3	ISO-10993-11	ISO	Biological Evaluation of medical Devices. Part 11- Tests for Systematic Toxieity	2009	8/30/2009
4	ISO-11135-1	ISO	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization	2007	05/01/2007
5	USP 34<731>	USP	Loss on Drying	34	11/1/2010
6	USP 34<791>	USP	pH	34	01/07/2012
7	AATCC-100	AATCC	Antibacterial Finishes on Texitic Materials. Assessment of	2004(R2008)	6/30/2008

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 4: Indication for Use Statement

510(k) Number (if known):

Device Name: Luofucon Silver Foam Dressing

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
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853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing layer is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof and semi permeable. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 6: Truthful and Accuracy Statement

Premarket Notification

Truthful and Accuracy Statement

for

Luofucon Silver Foam Dressing

I certify that, in my capacity as President of *Huizhou Foryou Medical Devices Co., Ltd.* believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Luofucon Silver Foam Dressing are truthful and accurate and that no material fact has been omitted.

Signature, Jinwen Mo

6/12/2014

Date

General Manager

Huizhou Foryou Medical Devices Co., Ltd.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7: Class III Summary and Certification

This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 8: Financial Certification or Disclosure Statement

This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9: Declarations of Conformity and Summary Reports

Our Submission is traditional 510(k). This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Executive Summary

This section composes the following:

- Section 10.1: Concise description of the device, including the indications for use and technology;
- Section 10.2: Device Comparison
- Section 10.3: Concise Summary for Performance Testing

Section 10.1: Concise Description of the Device (including the indications for use and technology)

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane foam and silver particles, which absorbs wound exudate and releases silver in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane foam material consists of metallic silver that provides effective protection of the dressing against microbial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days period, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The product in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, of the silver foam dressing has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer (non-wound contacting) side of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing as the adhesive to secure the dressing on patient skin surface. The film backing is waterproof and semi permeable. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing as the adhesive to secure the dressing on patient skin surface. The film backing is waterproof. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Section 10.2 Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 10.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has both single layered and double layered structure. This small difference does not impact the safety and efficacy of the two devices.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 10.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 10.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six

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(three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for four days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Section 10.3 Concise Summary for Performance Testing

The following Biocompatibility testing results are included in **Section 15** of this submission.

Purpose	Testing Standard
Cytotoxicity	ISO10993-5
Skin Irritation and Sensitization	ISO 10993-10
Systematic Toxicity	ISO 10993-11

The results show all materials are not cytotoxic, do not cause skin irritation, and sensitization, and have no systematic toxicity.

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The following bench performance testing results are included in **Section 18** of this submission for a representative lot.

Test items	Specification	Test Results	Test Method
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform	Visual
Dimension	Deviation ≤ ±5%	Conform	Calibrated ruler
Density	0.09-0.18 g/cm^3	0.110gram/m^3	Internal Method
Free Swell Absorption	≥10.0 g/g	13.8 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	4.98%	USP 34 <731> Loss on drying
pH	4.0～9.0	4.73	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	2.85 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria	AATCC 100: 2004

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we tested three (3) gram positive bacteria and three (3) gram negative bacteria, for the evaluation of broad spectrum antibacterial effectiveness of the silver foam dressing. The dressings are effective (>99.99% reduction) toward all six bacteria for three days.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 8
11.4 Test Results 9
11.5 List of All Materials Used 10
11.6 Manufacturing Process 11
11.7 Silver Compound Used in the Products and Silver Particle Size 13
11.8 Bonding Between Silver Particles and Silver Leachability 14
11.9 Antimicrobial Activity Spectrum (Profile) 17
11.10 Minimum Effective Concentration 17
11.11 Likely Silver Antibacterial Mechanism 18

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2).

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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A third adhesive variant, PU adhesive backing variant, also has a two-layered structure. A thin Polyurethane film layer, served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Different from the second variant, the backing layer is bigger in area than the thick soft layer of silver-encapsulated Polyurethane, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof and semi permeable. The product line is available in different sizes (See Table 11.3).

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a two layered structure. It uses a thin layer of non-woven material as the backing material. The non-woven material is laminated to the top of the thick soft layer of smooth elastic, breathable, and silver encapsulated polyurethane foam. Same as the third variant, the backing is also bigger in area than the thick soft layer of silver-encapsulated Polyurethane foam, and has pressure-sensitive adhesive on the backing to secure the dressing on patient skin surface. The backing layer is waterproof. The product line is available in different sizes (See Table 11.4).

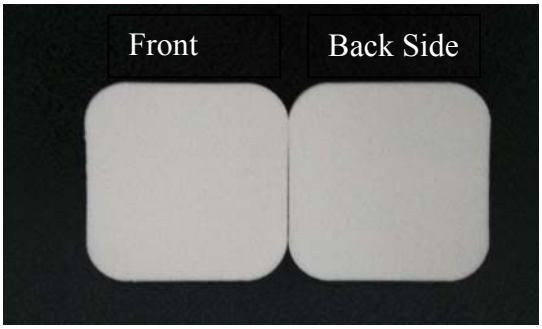
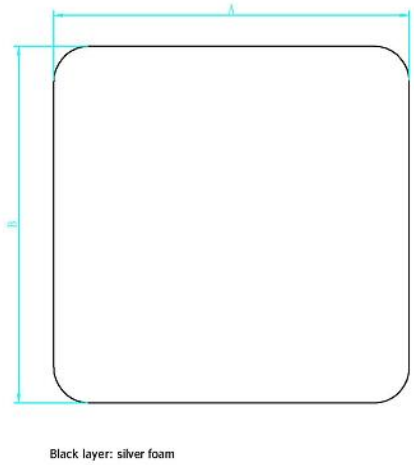
The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

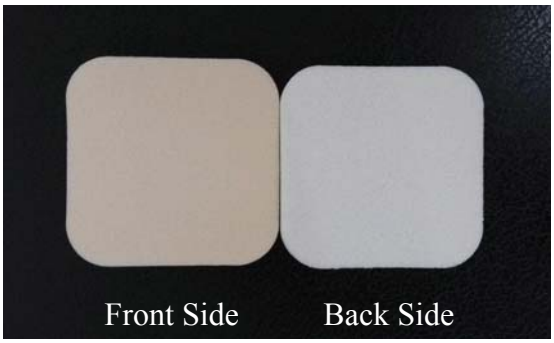
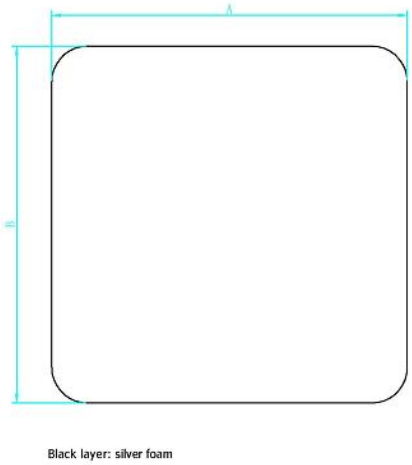
Representative Picture	**Drawing**
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

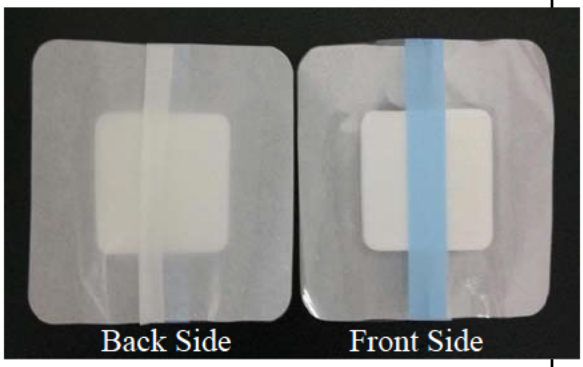
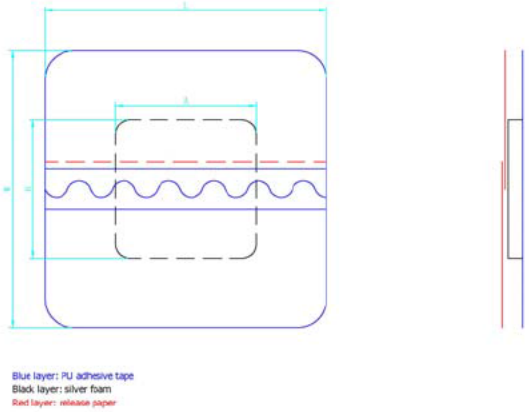
Representative Picture	**Drawing**
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

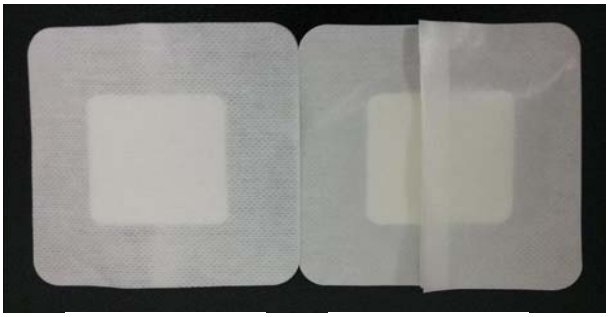
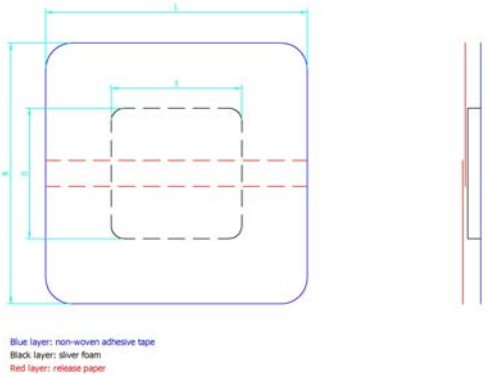
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	**Drawing** [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Packaging information is listed below:

Immediate Packaging:
Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging:

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Paper Box
Outer Packaging:
Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.5. The biological specifications are shown in Table 11.6.

Table 11.5: Physical Specification of Luofucon Silver Foam Dressing

Test items	**Specification**	**Test Method** [a]
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation $\leq \pm 5\%$	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying
pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]**:** Details are described in *Section 18: Performance Testing: Bench*

The biological specifications are shown in Table 11.6.

Table 11.6 Biological Specifications

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

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11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201305001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.5 and 11.6.

Table 11.5: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201305001, size 100 mm x 100 mm x 3 mm)

Test items	Specification	Test Results
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5%	Conform
Density	0.09-0.18 g/cm^3	0.110 gram/m^3
Free Swell Absorption	≥10.0 g/g	13.8 g/g
Loss on Drying	≤6%	4.98%
pH	4.0～9.0	4.73
Silver Content [a]	3±1 μg/cm^3	2.85 μg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

(b) (4)

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Table 11.6: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. One piece of silver dressing in the size of 100 x 100 x 3 mm were used and immersed in 20 mL of simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, 48, and 72 hours
Extraction temperature: 25 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry).

The test results are summarized in the Table 11.10 below. % of Total Silver is calculated using a nominal silver amount of 3 μg/cm^3 (total silver is 90 μg for 100 x 100 x 3 mm dressing)

The leachables are calculated as both daily leachable, which is the leached silver amount with 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

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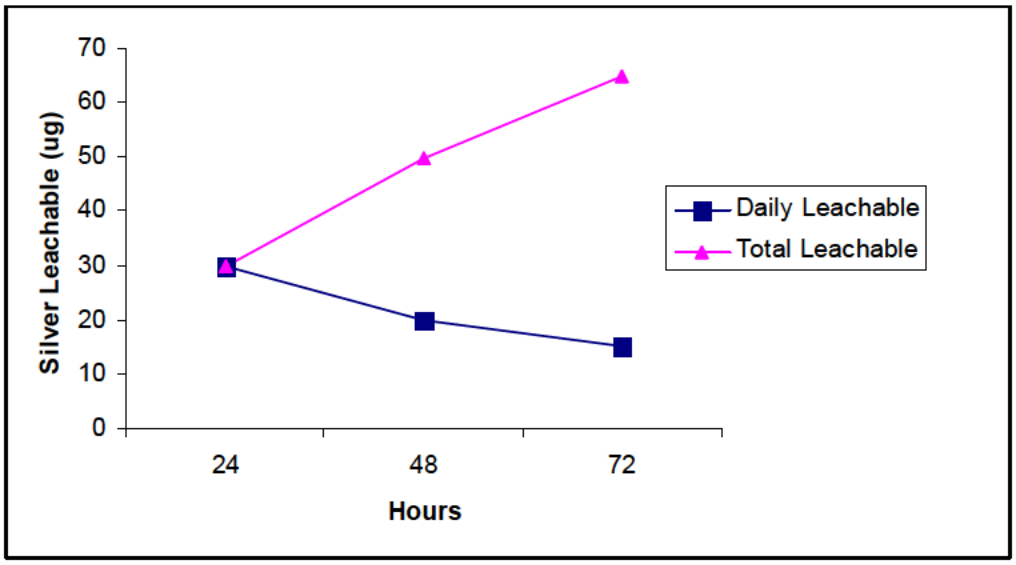
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Table 11.10: Silver Dressing Leachable Study. Test conditions are discussed above.

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Leachable (µg)	Daily leachable as % of Total Silver[a]	Total Leachable (µg)	Total Leachable as % of Total Silver[a]
24	1.50	20	30.0	33.3%	30.0	33.3%
48	0.99	20	19.8	22.0%	49.8	55.3%
72	0.75	20	15.0	16.7%	64.8	72.0%

[a]: 100 x 100 x 3 mm foam contains 90 µg silver, and was used in the calculation

Under this simulated condition, Luofucon Silver Foam Dressing leaches about 33.3% of the total silver during the first 24 hours, and leaches about 22.0%, and 16.7% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours about 72.0% of the total silver was leached out. This is also presented in the plot below:



This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

Since the nominal concentration of silver is 3±1 µg/ cm^3, after three days of recommended usage duration, at least 72.0% of silver is released, equivalent to at least 2.2 µg/cm^3. This number (2.2 µg/cm^3) will be shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, therefore causing much less skin discoloration effect.

Details of this experiment can be found in **Section 18**

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11.9 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.10 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.11 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 12: Substantial Equivalence Discussion

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

Table 12.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same

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Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 12.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 12.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and

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sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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Section 13: Proposed Labeling

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 6

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

RX Only
version: A/0

Product Name
LUOFUCON® Silver Foam Dressing

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment to accelerate healing process. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. LUOFUCON® Silver Foam Dressing can restrain the bacteria growing and reduce infection. LUOFUCON® Silver Foam Dressing has been tested *in vitro* and found to be effective against bacteria such as Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonsa aeruginosa and Klebsiella pneumoniae.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers (venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns (1st and 2nd degree)

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

Product Information:

Antibacterial Agent:	Silver particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 2-4ug/cm^3 silver

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity till day-3. The device has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Bacterial	Staphylococcus aureus ATCC 6538	Streptococcus pyogenes ATCC 19615	Enterococcus faecalis ATCC 29212
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherlchia coli ATCC 8739	Klesiella pneumonlae ATCC 4352	Pseudomonas aeruginosa ATCC 9027
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Instructions for Use
1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates. Initially it may be necessary to change the dressing every 24 hours. When the exudates reduce, the frequency may be slowdown.

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Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.
5. LUOFUCON® Silver Foam Dressing is intended for short-term use up to 28 days.

Adverse Reactions

LUOFUCON® Silver Foam Dressing has been subjected to independent standard for *in vitro* biocompatibility tests, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of the studies indicated that LUOFUCON® Silver Foam Dressing is safe for its intended use.

Specifications (All models are presented with both 3mm and 5mm thickness)

Foam or Foam With PU Backing (mm x mm)	PU or Non-woven Adhesive Backing (mm x mm)
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
120×100	150×150(100×100)
120×120	180×180(110×110)
150×100	
150×150	
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in sealed, cool and dry place and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture

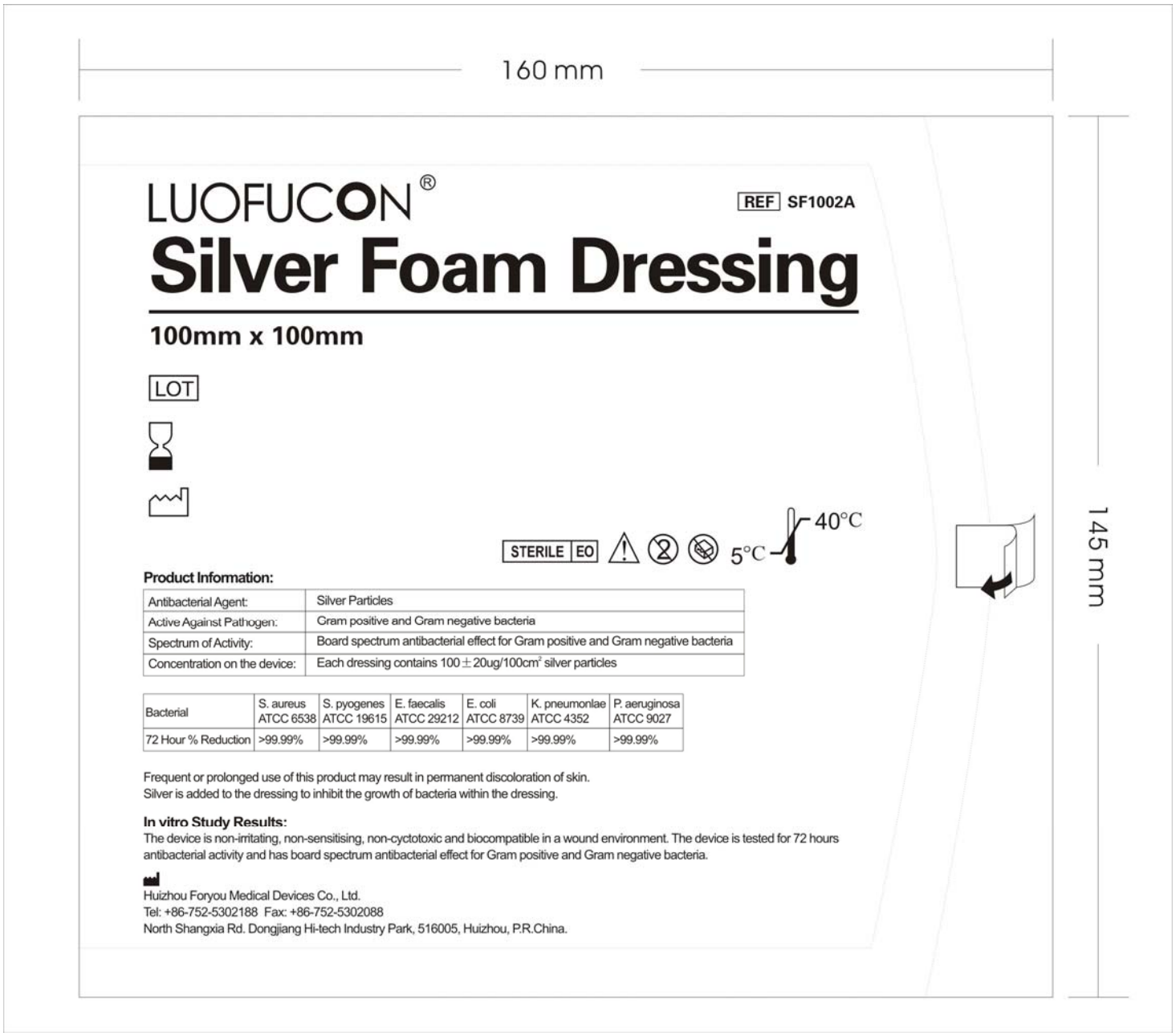
Manufacturer: Huizhou Foryou Medical Devices Co.,Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger



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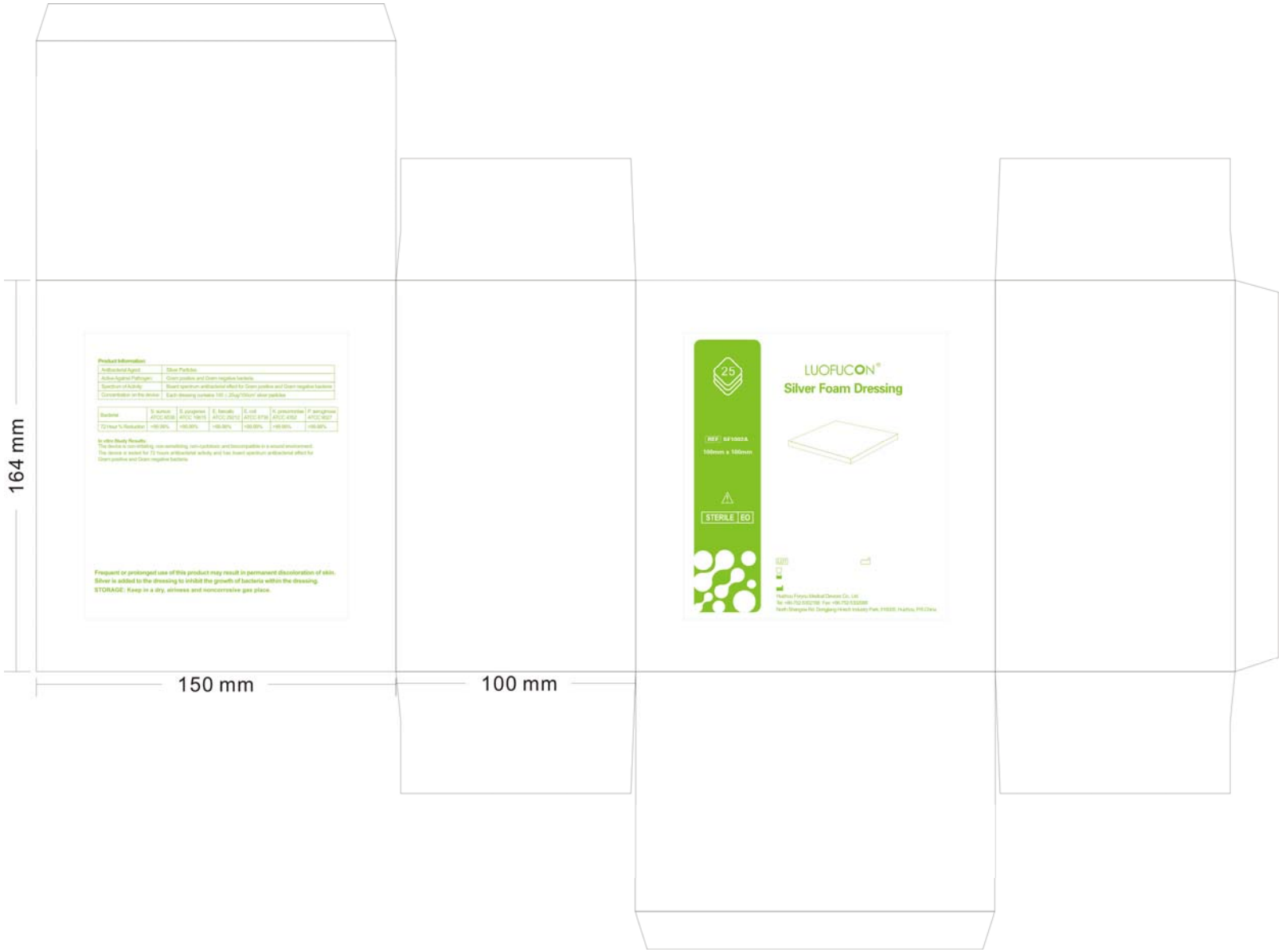
13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 13: Labeling: Prescription



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Section 14: Sterility and Shelf Life

Luofucon Silver Foam Dressing is sold directly to users after EtO sterilization validation to ISO 11135-1:2007, the sterilization method to be used is ethylene oxide with overkill approach. The details are the following:

14.1 Sterility Validation

The ethylene oxide method used to sterilize our "Luofucon Silver Foam Dressing" was validated following ISO 11135-1:2007. The method validation report can be found in **Appendix 1.**

Foam dressing without silver deposition was used to validate the procedure. Because of the general antibacterial activity of the silver ion, foam dressing without silver deposition has higher level of micro-organisms, thus represents the worst case scenario.

14.1.1 Reference of Standard: ISO-11135-1:2007

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: Yes. Foam dressing prior to silver deposition was used to validate the procedure. Justification: Foam dressing without silver is more difficult to sterilize (because silver itself is an antibacterial agent) thus represent the worst case scenario.

The name and address of test laboratory: In house

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Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	Yes
3	Terms and definitions	Yes
4	Quality management systems	Yes
5	Sterilizing agent characterization	Yes
6	Process and equipment characterization	Yes
7	Product definition	Yes
8	Process definition	Yes
9	Validation	Yes
10	Routine monitoring and control	Yes
11	Product release from sterilization	Yes
12	Maintaining process effectiveness	Yes

14.1.2. Validation Method

Sterilization method was validated following ISO-11135-1:2007. Ethylene oxide is used as the sterilization method. The method validation report is in Appendix 1.

Overkill approach (Half-cycle approach) is used following Annex B of the standard. A total of three consecutive experiments resulting in total inactivation of the biological indicators were performed in order to confirm the minimum exposure time. The specified exposure time doubles this minimum time. A cycle of short duration was also run to demonstrate the adequacy of the recovery technique.

Validation includes installation qualification, operational qualification, and process qualification.

Installation qualification (IQ) demonstrated that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

Operational qualification (OQ) demonstrated that the installed equipment is capable of delivering the specified process within defined tolerances.

The microbiological PQ was performed in the production chamber using defined process parameters selected to deliver less lethality than the specified sterilization process. The results demonstrated that, on application of the sterilization process, the specified requirements for sterility are met.

Physical PQ included a minimum of three planned qualification runs in which all the specified acceptance criteria are met. The results demonstrated reproducibility of the process and the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specifications.

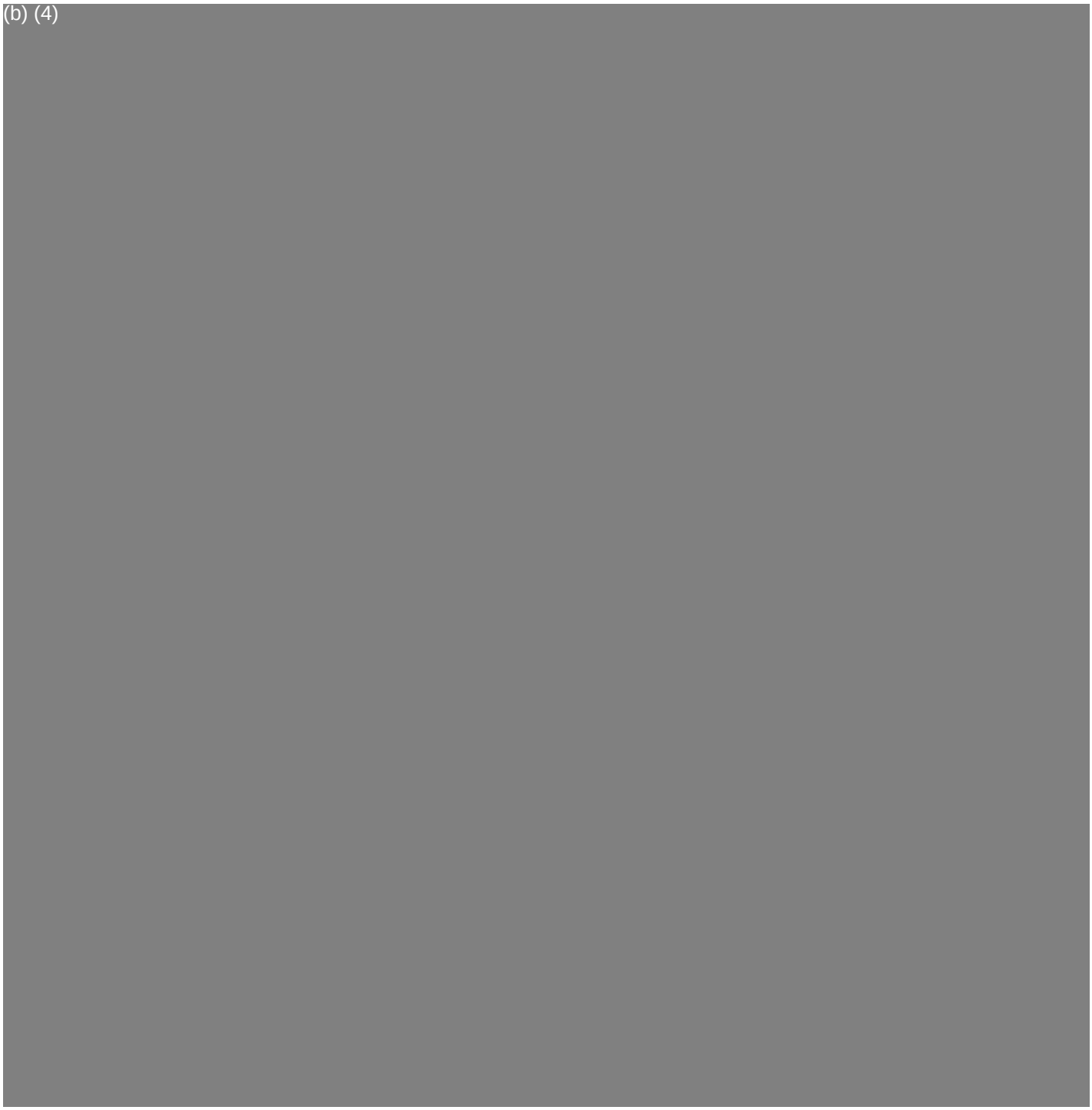
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Section 14: Sterility and Shelf

The validated sterilization parameters are the following:

(b) (4)



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(b) (4)

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14.1.4. SAL Level

The SAL level was found to be NMT 10^{-6} during our experiments.

14.2 Product Packaging

Luofucon Silver Foam Dressing is packaged in single use flexible package. Packages are supplied as preformed sterile barrier systems where all the seals have been formed except at the bottom. This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. A sealant layer is applied to allow heat-sealing of the two layers together.

The material, sterile barrier system, and product packaging are designed following the suggestions provided by ISO-11607-1. They have been proven to maintain sterility of terminally sterilized medical devices during storage, transportation, and distribution, until the point of use.

Table 14.3: Summary of packaging information involved in this submission

Immediate Packaging	Enforced paper- Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging	Paper Box
Outer Packaging	Corrugated Board Carton

14.3 Shelf Life Determination

The shelf life was determined by real time aging for products stored under ambient conditions. The proposed shelf life is two years.

14.3.1 Physical Properties

For real time aging test, products were stored under 25 ºC and 60% RH. Representative test results are summarized for Lot No.: S201107001; size100×100×3 mm; production date: July 12, 2011.

Both performance properties and packaging integrity were evaluated for up to two years.

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Physical properties were tested against product specifications as detailed in Section 11, except for silver content. Silver content is not expected to change over the course of time. All test results met specification and the results are summarized in the Table 14.4 below.

Table14.4: Representative Product Physical Properties for Two Year Real Time Aging Study

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×3±1mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.112	0.108	0.113
Absorbance	≥10g/g	12.6	12.3	11.2
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.47	4.44	4.56
Loss On Drying	≤6.0%	3.1%	4.1%	4.4%

14.3.2 Antibacterial Properties

Antibacterial properties were tested following standard AATCC-100:2004. Detailed test procedures are described in Section 18.7.2. In brief, an inoculum of the chosen challenge organism is absorbed into the test article and allowed to incubate for approximately 24 hours. The surviving challenge organisms are enumerated and compared to an untreated control.

Total of six bacteria (three Gram positive and three Gram negative) were tested:

Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 19615)
Enterococcus faecalis (ATCC 29212)
Escherichia coli (ATCC 8739)
Pseudomonas aeruginosa (ATCC 9027)
Klebsiella pneumoniae (ATCC 4352)

The antibacterial results after two years of ambient storage are presented in Table 14.5. The test was performed by Guangdong Detection Center of Microbiology, as an independent verification by third party.

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Table 14.5: Silver Foam Sample: Antibacterial activity results at Two Year Time Point. Size 100 x 100 x 3mm. The two year time point date was tested on Lot S201107001, manufacture date: July 12, 2011, test date: Sept 2013.

Bacterial	**Staphylococcus aureus ATCC 6538**			**Streptococcus pyogenes ATCC 19615**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	4.8×10^5/mL			4.7×10^5/mL		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28
Day-3 Inoculum Concentration	4.8×10^5			4.7×10^5		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28

Bacterial	**Enterococcus faecalis ATCC 29212**			**Escherlchia coli ATCC 8739**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.3×10^5/mL			5.2×10^5/mL		
Initial Contact time	2.1×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.0×10^6	2.0×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.32	>4.30	>4.32	>4.30	>4.30	>4.30
Day-3 Inoculum Concentration	5.3×10^5			5.2×10^5		
Initial Contact time	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.32	>4.3	>4.32	>4.30	>4.30	>4.30

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Bacterial	**Klesiella pneumonlae ATCC 4352**			**Pseudomonas aeruginosa ATCC 9027**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.0×10^5/mL			5.3×10^5/mL		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32
Day-3 Inoculum Concentration	5.0×10^5			5.3×10^5		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32

[a]: Inoculum Concentration is presented as CFU/ 1.0ml, while 4.0 mL was actually used each time to give 1.0-2.0 x 10^6 CFU.

The results show that the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

14.3.3 Packaging Integrity

Packaging integrity were tested for tensile strength (following suggestions by ASTM F88), dye penetration (following suggestions by ASTM F1929-98: 2004), and sterility. The results are summarized in Table 14.6. All pre-defined criteria were met for up to two years.

Table14.6: Representative Packaging Integrity Results for Two Year Real Time Aging Study

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.12	2.98	2.90
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

14.3.3 Conclusion for Aging Tests

Based on the above results, Luofucon Silver Foam Dressing is stable for up to two year under normal storage conditions. The product shelf life is designated as two years on the labeling.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 15: Biocompatibility

This section contains the following information

15.1 Cytotoxicity 2
15.1.1 Reference of Standard 2
15.1.2 Experimental 3
15.1.3 Results and Conclusion: 4
15.2 Sensitization Test 5
15.2.1 Reference of Standard 5
15.2.2 Experimental 6
15.2.3 Results and Conclusions: 8
15.3 Irritation Test 9
15.3.1 Reference of Standard 9
15.3.2 Experimental 10
15.3.3 Results and Discussions: 10
15.4 Systematic Toxicity 12
15.4.1 Reference of Standard 12
15.4.2 Experimental 13
15.4.3 Results and Discussions: 13

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Luofucon Silver Foam Dressing is used for the antibacterial and wound care purpose. Based on Table A.1 of ISO 10993-1, it is categorized as surface devices for bleached or compromised surface with prolonged duration. Cytotoxicity, sensitization, and irritation are needed for these devices. These tests are performed in accordance to ISO 10993-5 and ISO 10993-10. We also voluntarily added acute systematic toxicity test, which was performed per ISO 10993-11.

15.1 Cytotoxicity

Agar diffusion test described in ISO-10993-5:2009 was used to evaluate cytotoxicity of the material

In this test, test articles, positive and negative control samples were placed on top of agar in separate dishes. All dishes were incubated under appropriate conditions before the cells were stained with Neutral red. The decolorization zone and the cell lysis were examined using inverted microscope. The results demonstrated that there was no cytotoxicity for the test article, Luofucon Silver Foam Dressing.

15.1.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected:

(a) The standard allow the tester to select from performing test on extract of the sample, or performing test on the sample itself (section 4.1 of the standards). We choose to perform test on the sample itself

(b) For the same reason above, section 8.4 of the standard: Test by Indirect Contact (Agar Diffusion) was followed, as a proven and well accepted method for solid material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	Sample and Control Preparation	Yes.
5	Cell lines	Yes
6	Culture medium	Yes
7	Preparation of Cell Stock Culture	Yes
8	Test procedures	Yes. Followed procedures in 8.4.1
9	Test report	Yes
10	Assessment of results	Yes
11	Annex A-D	N/A

15.1.2 Experimental

Indirect test/Agar diffusion method was used in the determination of cytotoxicity.

More experimental details can be found in test report attached in **Appendix 1** of this submission.

Cell Preparation Procedure:
L-929 Mouse fibroblast cells were proliferated following normal procedures before they were trypsinized, collected, and adjusted to a concentration of 1.3 x 10^5/mL.

Growth Inhibition Test Procedure:
The liquid nutrient medium from each Peri dish was aspirated and replaced with freshly prepared 2.0 mL agar medium. After the agar medium solidified at room temperature, a 10.0 mm diameter disc portion of the test article was placed symmetrically on agar surface. Similarly, negative and positive control samples were also placed on top of agar. All Peri dishes were incubated at 37 °C in 5% CO_2 for 24 hours.

After incubation, the cells were stained with Neutral Red. The decolorization zone and the cell lysis were examined using inverted microscope.

Positive and Negative Control
High density polyethylene was used as the negative control, MEM medium with 0.5% phenol was used as positive control.

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Acceptance Criteria: Reactivity was graded based on Table 2 of ISO-10993-5 (also see table below). Score of negative control should be less than 1. Score of the positive control should be higher than 3. All readings from the test article should be no more than 2 to demonstrate none cytotoxicity.

Table 15.1 Reactivity Grade for Cytotoxicity Test

Grade	Description of the Zone
0	No detectable Zone around or under the sample
1	Some malformed or degenerate cells under the sample
2	Zone limited to area under the sample
3	Zone extends 0.5 to 1.0 cm beyond the sample
4	Zone greater than1 cm in extension from the sample

15.1.3 Results and Conclusion:

Three replicates were tested for each samples and controls. For all replicated tests, the reactivity grades for positive control, negative control, and sample are 4, 0, and 2, respectively. Based on ISO-10993-5, a numerical grade of greater than 2 (≥3) is considered cytotoxic. The test article, Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing has mild reactivity and in general is considered not toxic.

Table 15.2 Cytotoxicity Test Results

Group	Grade	Reactivity
Positive Control		
(1)	4	Severe
(2)	4	Severe
(3)	4	Severe
Negative Control		
(1)	0	None
(2)	0	None
(3)	0	None
Test Article		
(1)	2	Mild
(2)	2	Mild
(3)	2	Mild

The negative and positive control samples meet the requirement specified in acceptance criteria.

The test report (SDWH 2012-22572) can be found in **Appendix 1** of this submission.

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15.2 Sensitization Test

In selecting a new material for human contact in medical applications, it is important to ensure that the material does not stimulate the immune system to produce allergic response. This effect can be evaluated using procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". The maximization method was used.

15.2.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 7 of the standard: Delayed hypersensitivity tests. There are two most commonly used methods for delayed hypersensitivity. Maximization test was selected based on the nature and application of our materials. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes

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5	Pretest considerations	Yes
6	Irritation tests	Will be discussed in Section 15.3. of this submission
7	Sensitization tests	Yes. Note: There are two most commonly used methods for delayed hypersensitivity. The maximization was selected based on the nature and application of our material. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.
8	Key factors in the interpretation of test results	Yes

15.2.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

Number of Animals: Twenty test animals (ten for sesame oil and ten for 0.9% sodium chloride), five positive control animals, and ten negative control animals (five for sesame oil and five for 0.9% sodium chloride), each weighing 300-500 grams.

Extraction Condition:
The test article was extracted with sesame oil (as non-polar extract) and 0.9% sodium chloride (as polar extract), respectively, in the volume of $3cm^2$/mL. The extractions were performed at 37 °C for 72 hours.

Control Solutions:
Both sesame oil and 0.9% sodium chloride were used as negative control.
10 mg/mL 2,4 Dinitrofluorobenzene (DNFB) in acetone was used as positive control.

Intradermal Induction Phase
A pair of 0.1 ml intradermal injections were made of each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent (sesame oil or 0.9% sodium chloride).

Site B: The test sample (undiluted extract); negative control animals were injected with the chosen solvent alone (sesame oil for non-polar extract or 0.9% sodium chloride for polar extract); positive control animals were injected with the 10 mg/mL DNFB acetone solution alone.

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Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extract (50 %); the control animals were injected with an emulsion of 50:50 sesame oil or sodium chloride with Freund's complete adjuvant; positive control animals were injected with an emulsion of 50:50 10 mg/mL DNFB acetone solution and Freund's complete adjuvant.

Site A	Site A
Site B	Site B
Site C	Site C

Topical Induction Phase

At 6 days after completion of the intradermal induction phase, the test sample (using the concentration selected for site B) was topically administrated to the intrascapular region of each animal, using a filter paper (approximately 8 cm^2) soaked in the test sample extract, to cover the intradermal injection sites. The area was pretreated with 10 % sodium dodecyl sulfate massaged into the skin 24 h before the filter paper was applied. Filter paper was secured with elastic band. They were removed after 48 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Challenge phase

14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. Filter paper soaked in the test sample extract was administrated by topical application to upper flank of each animal (that areas were not treated during the induction stage). The patch was secured, and removed after 24 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Observation of animals

Challenge skin sites of the test and control animals were observed 24 h and 48 h after removal of the dressings. Observations were made with proper lighting.
Skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading for each challenge site and at each time interval.

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Readings were made without knowledge of the treatment. The test results were based on incidence and severity of the sensitization reaction.

Table 15.3: Grading Scale for Sensitization Test

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

15.2.3 Results and Conclusions:

Clinical Observations: None of the animals in the study showed abnormal clinical signs

Main Test Dermal Observations:
No irritations were observed on the test animals and negative control animals during the induction phase, for both sesame oil and 0.9% sodium chloride extracted samples.

The average grade for positive control animals is 2 from both reports SDWH 2013-21069 and SDWH 2013-21070.

None of the test animals challenged with the test article were observed with sensitization response at any time point of the challenge phase, indicating a 0% incidence. The severity was calculated as "0" at each time point, for both sesame oil and 0.9% sodium chloride extracted samples.

Conclusion:
Based on the above results, material used in the Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing does not elicit a sensitization response.

The following test reports can be found in **Appendix 1** of this submission.
SDWH 2013-21824 for Sesame Oil and negative control
SDWH 2013-21714 for Sodium Chloride and negative control
SDWH 2013-21069 for positive control
SDWH 2013-21070 for positive control

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.3 Irritation Test

The irritation test was conducted following procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". Human test was not conducted, as our products are made of solid material, thus don't have a high human exposure concentration, such as cosmetics.

15.3.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 6 of the standard: Irritation Tests. Section 6.4: Human skin irritation test is not performed. Human tests usually are performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes
5	Pretest considerations	Yes
6	Irritation tests	Yes. Note: Section 6.4: Human skin irritation test is not performed. Human tests usually are

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.
7	Sensitization tests	Discussed in Section 15.2 of this submission
8	Key factors in the interpretation of test results	Yes

15.3.2 Experimental

Test articles and controls were cut into pieces in the size of 2.5 cm x 2.5 cm.

Only animals with healthy skin were used. 4 sites were designated on each rabbit, with 2 sites on each side of the back, for test and control purpose, respectively. Total three animals were used.

Test material and control were applied directly to the shaved skin of three adult New Zealand White rabbits. After minimum four hours exposure, the patches were removed. Observations for skin irritations were conducted after 1, 24, 48, and 72 hours. The scores were totaled and averaged for the test article and negative control. The primary irritation index was then calculated.

Table 15.4: Grading Scores System Used in Irritation Test

Response category	Comparative Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2-4.9
Severe	5-8

15.3.3 Results and Discussions:

The results are summarized in the table below.

Table 15.5: Summary of Irritation Test Results

Sample	Test Article	Negative Control	Positive Control
1 hour	0.0	0.0	2
24 hours	0.0	0.0	3
48 hours	0.0	0.0	3
72 hours	0.0	0.0	2

The mean scores for both the test article and negative control are 0 for 1, 24, 48, and 72 hours. Test article does not induce irritation to skin.

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The mean scores for positive control are 2, 3, 3, 2 for 1, 24, 48, and 72 hours.

The test report SDWH 2013-21715 for test article and negative control, and test report SDWH 2013-20111 for positive control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.4 Systematic Toxicity

The acute systematic toxicity test was conducted following procedures described in ISO 10993-11:2006 Standard, "Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity". The acute systematic toxicity was evaluated by the intraperitoneal injection of the extraction solution at 50 mL/kg. The symptom of toxicity and weight growth of test mice were observed and recorded daily. The results demonstrated the lack of systematic toxicity of the test article.

15.4.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

In Section 6 of the standard: Acute systematic toxicity by intraperitoneal application described in section 6.5.5. was followed

Any requirements that were not applicable to the device: Section 6.6 (Subacute systematic toxicity), Section 6.7 (Subchronic systematic toxicity), Section 6.8 (Chronic toxicity and carcinogenicity), and Section 7 (Pyrogenicity).

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Definitions	N/A
4	Test Sample Requirements and Recommendations	Yes
5	Method for Extraction from Medical devices	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6	Selection of Test Procedures for Systematic Toxicity	Yes. Note: Acute Systematic Toxicity described Section 6.5.5 was followed.
7	Selection of Test Procedures for Pyrogenicity	Not performed
8	Assessment of Results	Yes
9	Test report	Yes

15.4.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

The test article was extracted with sesame oil or saline (0.9% sodium chloride) in the volume of 30 cm^2/10 mL. The extraction was at 37 °C for 72 hours. The sample was completely dissolved as clear solution.

Sesame oil or saline was used as control solution.

Twenty mice were randomly divided into four groups: five mice for sesame oil test group, five mice for saline test group, five mice for sesame oil control group, and five mice for saline control group. Sample extract or control solution (saline) was administered by intraperitoneal injection at a dose of 50 mL/kg. The instant response of each mouse was observed after injection. Furthermore, monitor and record the status of the test and control animals daily for three days.

15.4.3 Results and Discussions:

Acceptance Criteria:
Within the 72 hours of observation period, the toxicosis response of the test group is no greater than the control group.

Results and Discussions
Within the monitoring period of 4, 24, 46, and 72 hours, the toxicosis response of the test group was no greater than the control group for both Saline and Sesame Oil groups. In addition, weight continued to increase for both the test and control group animals.

Conclusions
The test material showed no sign of acute systematic toxicity.

The test reports (SDWH 2013-21825, SDWH 2013-21716) for test article and negative control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 16: Software

Our device does not contain software. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 17: Electromagnetic Compatibility and Electrical Safety

Our device does not contain electrical components. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18: Performance Testing – Bench

This section contains the bench performance testing results for the Luofucon Silver Foam Dressing described in this submission. The tests including the following:

Section 18.1 Density 2
Section 18.1.1 Experimental: 2
Section 18.1.2 Results and Discussions: 2
Section 18.2 Absorbency Test: Free Swell Absorption Capacity 3
Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002 3
Section 18.2.2 Experimental: 4
Section 18.2.3 Results and Discussions: 4
Section 18.3: Loss on Drying 5
Section 18.3.1: Reference to Standard USP 34 General Chapter <731> 5
Section 18.3.2: Experimental 5
Section 18.3.3: Results and Discussions 6
Section 18.4: pH Value 7
Section 18.4.1: Reference to Standard USP<791> 7
Section 18.4.2: Experimental 7
Section 18.4.3: Results and Discussions: 8
Section 18.5: Silver Content 9
Section 18.5.1: Reference to General Test Procedure EPA 6010C-2007 9
Section 18.5.2: Experimental 10
Section 18.5.3: Results and Discussions: 11
Section 18.6: Antibacterial Activity 12
Section 18.6.1: Reference to the AATCC 100-2004 12
Section 18.6.2: Experimental 13
Section 18.6.3: Testing Results 16
Section 18.6.4: Discussion of Testing Results 19
Section 18.7: Determination of Minimum Effective Concentration 21
Section 18.7.1: Experimental 21
Section 18.7.2: Results 21
Section 18.7.3: Discussions and Conclusion 24
Section 18.8: Silver Leachablity Study 25
Section 18.8.1: Experimental 25
Section 18.8.2: Results and Discussions: 26

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 19: Performance Testing: Animal

No animal testing was performed for this device.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 20: Performance Testing – Clinical

No clinical testing is not necessary for our device. This section does not apply to our device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 1 Form FDA 3654: Standards Data Report for 510(k)

The following FDA recognized Standards are referenced in this submission, and their respective Form 3654's are included in this Attachment 1:

- Standard Data Report for ISO 10993:5
- Standard Data Report for ISO 10993:10
- Standard Data Report for ISO 10993:11
- Standard Data Report for ISO 11135:1
- Standard Data Report for EN13726
- Standard Data Report for USP 34 <731>
- Standard Data Report for USP 34 <791>
- Standard Data Report for AATCC-100

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-5:2009: Biological Evaluation of medical Devices", Part 5 – Tests for In Vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO-10993-5:2009: Biological Evaluation of medical Devices", Part 5 – Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Sample and control preparation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
The standard (Section 4.1) allows the options of performing test on extract of the sample, or performing test on the sample itself

DESCRIPTION
We choose to perform test on the sample itself

JUSTIFICATION
Perform test on the sample itself allows direct evaluation of the cytotoxicity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test procedures	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Standard provide three options: extraction, direct contact, and indirect contact

DESCRIPTION
Section 8.4. of the standard:Test by Indirect Contact (Agar Diffusion) was followed

JUSTIFICATION
Test by Indirect Contact (Agar Diffusion) is a well accepted method for solid material.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-10:2010: Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO-10993-10:2010: Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Section 6.4: Human skin irritation test was not performed

DESCRIPTION

Section 6.4: Human skin irritation test was not performed

JUSTIFICATION

Human tests are needed for chemicals that human exposure is high (cosmetics). Our product is not in this category.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Standard provide two options for hypersensitivity. Maximization method was used in our test.

DESCRIPTION

Maximization method was used in our test.

JUSTIFICATION

Maximization method is more suited for single chemical. Buehler method is more suited for composite chemicals.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-11:2006: Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO-10993-11:2006: Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of Test Procedures for Systematic Toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
The standard (Section 6) allows the options of systematic toxcity tests based on mode and duration of patient contact

DESCRIPTION
We choose to perform acute systematic toxicity (Section 6.5).

JUSTIFICATION
Our product has modest patient contact duration.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Selection of Test Procedures for Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
This test is not performed

DESCRIPTION
Pyrogenicity test is not performed

JUSTIFICATION
Our product is not expected to have material related pyrogens

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1:2007: Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and r

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-331	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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STANDARD TITLE
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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 13726-1:2002: Test methods for primary wound dressings — Part 1: Aspects of absorbency

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 13726-1:2002: Test methods for primary wound dressings — Part 1: Aspects of absorbency

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Test methods for absorbency	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Exclusion from Standard

DESCRIPTION

Only Free Swell Absorptive Capacity Test (Sec 3.2) was performed. Sections 3.3-3.7 were not performed.

JUSTIFICATION

Only Free Swell Absorptive Capacity is relevant to our product and in our product specifications.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

USP 34 General Chapter <731>; Loss on Drying

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP 34 General Chapter <791>: pH

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AATCC Test Method 100-2004 Antibacterial Finishes on Textile Materials: Assessment of

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AATCC Test Method 100-2004 Antibacterial Finishes on Textile Materials: Assessment of

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Evaluation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Selection of an option

DESCRIPTION
Section 11.2 of the standard allows calculation of %reduction by three different methods. We choose to use method 1.

JUSTIFICATION
B is lager than C, therefore, method 1 should be used

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Test Organisms	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Deviation to adapt the standard to the device

DESCRIPTION
The Standard mentioned two bacteria. We tested three Gram positive bacteria and three Gram negative bacteria.

JUSTIFICATION
Testing more bacteria allows better evaluation of the antibacterial property of our device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Quantitative Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Deviation to adapt the standard to the device

DESCRIPTION
The Standard suggested using (1-2) e5 inoculum per sample. We used (1-2) e6 inoculum per sample

JUSTIFICATION
Inoculation at (1-2) e6 allows us to evaluate Log 4 bacterial reduction.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Huizhou Foryou Medical Devices Co., Ltd.

2. Date of the Application/Submission Which This Certification Accompanies
06/06/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Huizhou

State/Province/Region
Guangdong

Country
China

ZIP or Postal Code
516005

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (086) 0752-5302188

(Fax): (086) 0752-5302020

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: Silver Foam Dressing

Classification Name: Dressing, wound, Drug

Trade Name: Luofucon Silver Foam Dressing

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Charles Shen	Official Correspondent

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	853 Dorchester LN, Unit-B
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	New Milford
State/Province/Region	NJ
Country	USA
ZIP or Postal Code	07646

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 001-608-217-9358

(Fax): 001-425-930-2155

14. Date of Certification

05/30/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Charles Shen

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

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Appendix 1: Test Reports

The Following test report is included in this Appendix

Biocompatibility:
Cytotoxicity: Report #: SDWH-2012-22572
Skin Irritation: Report #: SDWH-2013-21715
Skin Sensitization (Sesame Oil): Report #: SDWH-2013-21824
Skin Sensitization (NaCl): Report #: SDWH-2013-21715
System Toxicity (Sesame Oil): Report #: SDWH-2013-21825
System Toxicity (NaCl): Report #: SDWH-2013-21716

Sterilization Validation Report: #: JS-75-653

Antibacterial Test Report

Lufucon Silver Foam Dressing: Report #: 2013FM3413Ea
Lufucon Foam Control Dressing (without Silver): Report #: 2013FM3826E
Neutralization Test: Report #: 2013FM4107E

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1-CD

K141619/S1

FDA CDRH DMC

JUL 23 2014

Received

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: Revision for 510(k) Number: K141619, Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are also summarized below:

1. Administrative (9): There has been no prior submission. Identification statement has been added to Section 3 (Cover Letter)

2. Device Description (11): Chemical composition and function of the non-woven material layer in the fourth variant of your device has been added to page 3 of Section 11

3. Device Description (12): Description about the thicknesses of the secondary layers in the second, third, and fourth variants of your device have been added to pages 2-3, and page 9 (Table 11.5) of Section 11.

4. Product Labeling (17): Zoomed in product labeling has been added in Section 13 for legible reading.

5. Biocompatibility (29): Complete materials of construction for each of the variants of your device, including secondary layers and any adhesives have been added to page 2 of Section 15.

6. Other: Section 5 and Section 10 are also updated to be consistent with changes in Section 11.

43

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles shen

Charles Shen, Official Correspondent
Date: July 20, 2014

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles Shen, Official Correspondent
Date: July 20, 2014

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 3: Cover Letter

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: 510(k) Premarket Notification for Huizhou Foryou Medical Devices Co., Ltd.
User Fee Identification Number: MD6075572-956733

Dear Sir/Madam:

Please find enclosed are two copies of a premarket notification for silver foam dressing manufactured by *Huizhou Foryou Medical Devices Co., Ltd.* The Luofucon Silver Foam Dressing described in this premarket notification is substantially equivalent to:

Two copies are included: One paper copy and one eCopy.
The eCopy is an exact duplicate of the paper copy.
There were no prior submissions with FDA for the subject device.

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Below are details of our submission:

Administrative Information:
Type of 510(k) submission: Traditional

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery
510(k) Submitter:	Huizhou Foryou Medical Devices Co., Ltd.
Contact Person:	Charles Shen, Official Correspondent, 001-608-217-9358

Preference for continued confidentiality (21 CFR 807.95): Yes
Any FDA Formal correspondence: None

Basis for the Submission:
New Device

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission includes extensive trade secret and commercial information which is privileged or confidential, in accordance with 21 CFR 807.95, is not available for public disclosure.

In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. A 510(k) Screening Checklist, Indication for Use Statement, and Truthful and Accurate Statement are also included.

Further, in accordance with MDUFMA, we have submitted the required user fee of $4,840. A copy of the Medical Device User Fee Cover Sheet is attached.

If you have any questions regarding this notification or require additional information, please contact me at 608-217-9358. My facsimile number is 425-9302155, and my email address is: cyshen@aol.com

Sincerely,

Charles Shen

Charles Shen

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 $\mu g/cm^3$ silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

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Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Executive Summary

This section composes the following:

- Section 10.1: Concise description of the device, including the indications for use and technology;
- Section 10.2: Device Comparison
- Section 10.3: Concise Summary for Performance Testing

Section 10.1: Concise Description of the Device (including the indications for use and technology)

Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Indications for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane foam and silver particles, which absorbs wound exudate and releases silver in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane foam material consists of metallic silver that provides effective protection of the dressing against microbial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days period, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

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All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The product in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Section 10.2 Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 10.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial	Three days	Three days [a]

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Duration		
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has both single layered and double layered structure. This small difference does not impact the safety and efficacy of the two devices.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 10.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 10.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for four days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

Section 10.3 Concise Summary for Performance Testing

The following Biocompatibility testing results are included in **Section 15** of this submission.

Purpose	Testing Standard
Cytotoxicity	ISO10993-5
Skin Irritation and Sensitization	ISO 10993-10
Systematic Toxicity	ISO 10993-11

The results show all materials are not cytotoxic, do not cause skin irritation, and sensitization, and have no systematic toxicity.

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The following bench performance testing results are included in **Section 18** of this submission for a representative lot.

Test items	Specification	Test Results	Test Method
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform	Visual
Dimension	Deviation ≤ ±5%	Conform	Calibrated ruler
Density	0.09-0.18 g/cm^3	0.110gram/m^3	Internal Method
Free Swell Absorption	≥10.0 g/g	13.8 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	4.98%	USP 34 <731> Loss on drying
pH	4.0～9.0	4.73	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	2.85 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria	AATCC 100: 2004

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we tested three (3) gram positive bacteria and three (3) gram negative bacteria, for the evaluation of broad spectrum antibacterial effectiveness of the silver foam dressing. The dressings are effective (>99.99% reduction) toward all six bacteria for three days.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 9
11.4 Summary of Test Results 10
11.5 List of All Materials Used 11
11.6 Manufacturing Process 12
11.7 Silver Compound Used in the Products and Silver Particle Size 14
11.8 Bonding Between Silver Particles and Silver Leachability 15
11.9 Antimicrobial Activity Spectrum (Profile) 18
11.10 Minimum Effective Concentration 18
11.11 Likely Silver Antibacterial Mechanism 19

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odour reduction results from the antibacterial effect in the dressing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

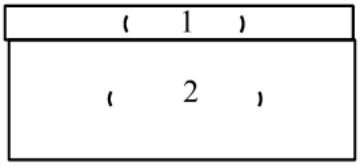
The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2, Table 11.5).

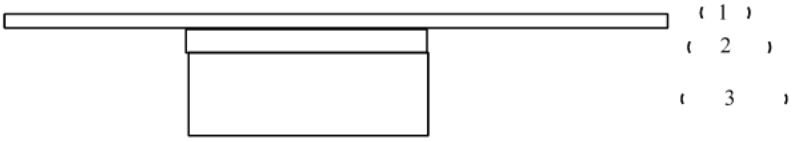
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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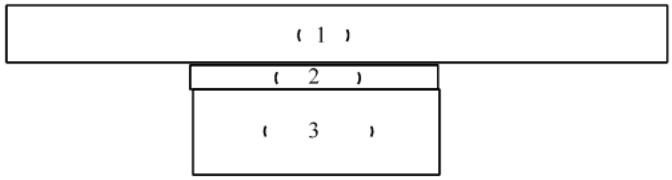
Illustrative drawing of the second variant: (1)) Thin polyurethane backing layer for cosmetic purpose (2) Thick polyurethane wound contacting layer

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.3, Table 11.5).



Illustrative drawing of the third variant: (1) Thin PET layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.4, Table 11.5).



Illustrative drawing of the fourth variant: (1) Non woven layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

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For the third and fourth variants, the adhesive is composed of 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

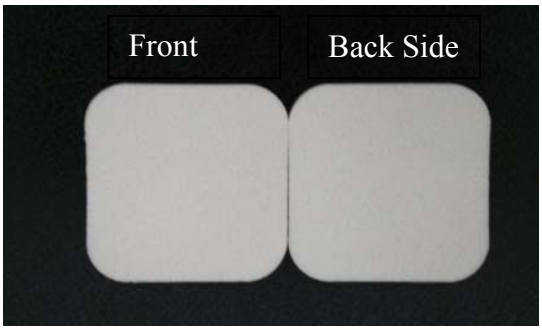
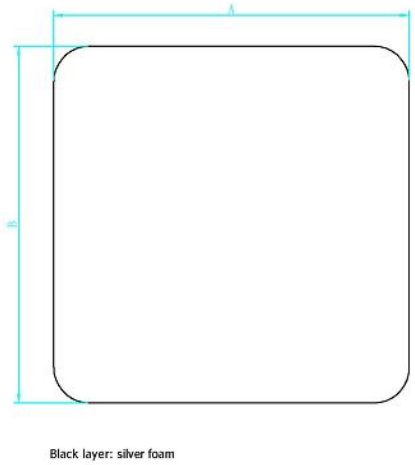
Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below. Secondary layer information are summarized in Table 11.5.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11: Device Description

Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

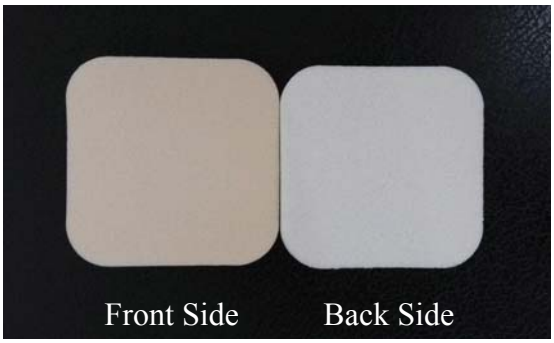
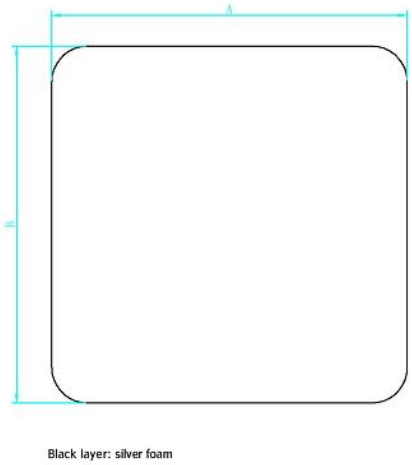
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

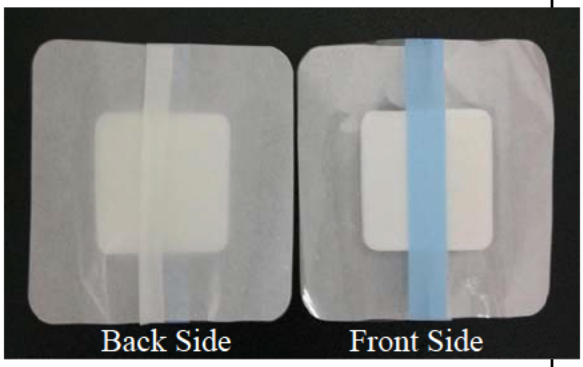
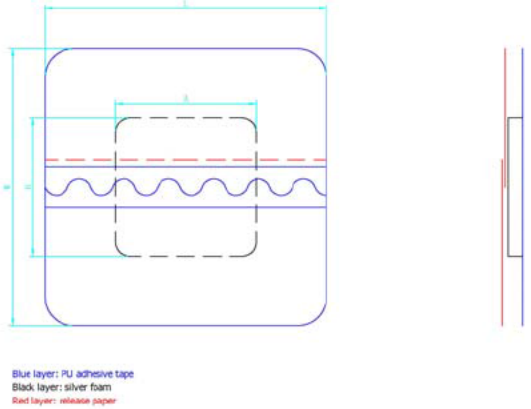
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

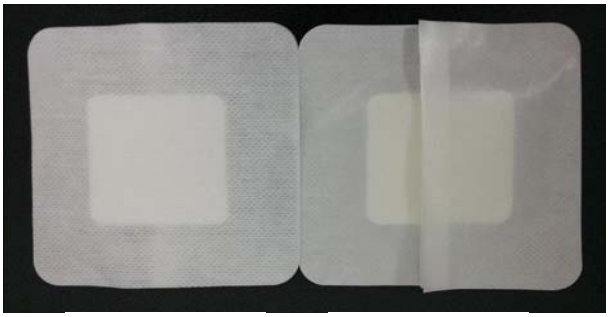
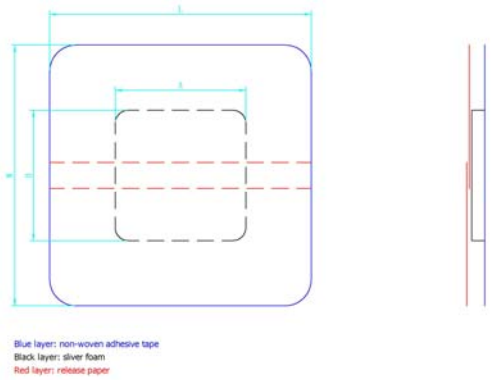
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

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Table 11.5: Secondary Layer Information Summary

Variant	Variant	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Packaging information is listed below:

Immediate Packaging:
Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging:
Paper Box
Outer Packaging:
Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.6. The biological specifications are shown in Table 11.7.

Table 11.6: Physical Specification of Luofucon Silver Foam Dressing

Test items	**Specification**	**Test Method [a]**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation $\leq \pm 5\%$	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying

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pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details are described in *Section 18: Performance Testing: Bench*

The biological specifications are shown in Table 11.7.

Table 11.7 Biological Specifications

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201305001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.8 and 11.9.

Table 11.8: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201305001, size 100 mm x 100 mm x 3 mm)

Test items	**Specification**	**Test Results**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5%	Conform
Density	0.09-0.18 g/cm^3	0.110 gram/m^3

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Free Swell Absorption	≥10.0 g/g	13.8 g/g
Loss on Drying	≤6%	4.98%
pH	4.0～9.0	4.73
Silver Content [a]	3±1 μg/cm^3	2.85 μg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

[a:] Incoming Quality Control

Table 11.9: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. One piece of silver dressing in the size of 100 x 100 x 3 mm were used and immersed in 20 mL of simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, 48, and 72 hours
Extraction temperature: 25 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 20 mL of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry).

The test results are summarized in the Table 11.10 below. % of Total Silver is calculated using a nominal silver amount of 3 μg/cm^3 (total silver is 90 μg for 100 x 100 x 3 mm dressing)

The leachables are calculated as both daily leachable, which is the leached silver amount with 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

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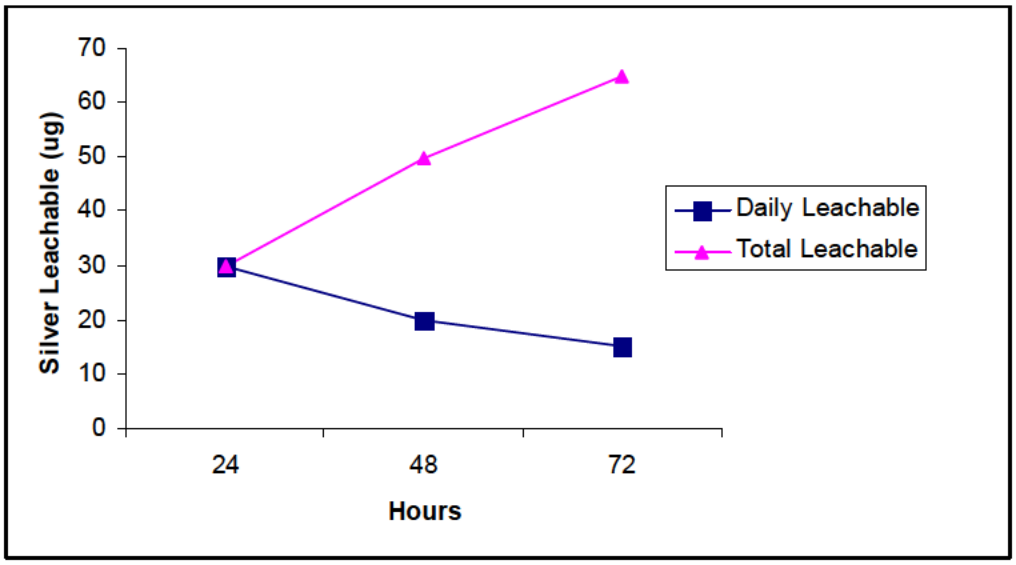
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Table 11.13: Silver Dressing Leachable Study. Test conditions are discussed above.

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Leachable (µg)	Daily leachable as % of Total Silver[a]	Total Leachable (µg)	Total Leachable as % of Total Silver[a]
24	1.50	20	30.0	33.3%	30.0	33.3%
48	0.99	20	19.8	22.0%	49.8	55.3%
72	0.75	20	15.0	16.7%	64.8	72.0%

[a]: 100 x 100 x 3 mm foam contains 90 µg silver, and was used in the calculation

Under this simulated condition, Luofucon Silver Foam Dressing leaches about 33.3% of the total silver during the first 24 hours, and leaches about 22.0%, and 16.7% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours about 72.0% of the total silver was leached out. This is also presented in the plot below:



This test condition represents real conditions of use because simulated wound exudates were used, and 20 mL daily volume mimics moderate to heavily exuding.

Since the nominal concentration of silver is 3±1 µg/ cm^3, after three days of recommended usage duration, at least 72.0% of silver is released, equivalent to at least 2.2 µg/cm^3. This number (2.2 µg/cm^3) will be shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, therefore causing much less skin discoloration effect.

Details of this experiment can be found in **Section 18**

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11.9 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.10 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.11 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 13: Proposed Labeling

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 6

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

RX Only
version: A/0

Product Name
LUOFUCON® Silver Foam Dressing

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment to accelerate healing process. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. LUOFUCON® Silver Foam Dressing can restrain the bacteria growing and reduce infection. LUOFUCON® Silver Foam Dressing has been tested *in vitro* and found to be effective against bacteria such as Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonsa aeruginosa and Klebsiella pneumoniae.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers (venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns (1st and 2nd degree)

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

Product Information:

Antibacterial Agent:	Silver particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 2-4ug/cm^3 silver

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity till day-3. The device has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Bacterial	Staphylococcus aureus ATCC 6538	Streptococcus pyogenes ATCC 19615	Enterococcus faecalis ATCC 29212
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherlchia coli ATCC 8739	Klesiella pneumonlae ATCC 4352	Pseudomonas aeruginosa ATCC 9027
72 Hour %Reduction	>99.99%	>99.99%	>99.99%

Instructions for Use
1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates. Initially it may be necessary to change the dressing every 24 hours. When the exudates reduce, the frequency may be slowdown.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.
5. LUOFUCON® Silver Foam Dressing is intended for short-term use up to 28 days.

Adverse Reactions

LUOFUCON® Silver Foam Dressing has been subjected to independent standard for *in vitro* biocompatibility tests, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of the studies indicated that LUOFUCON® Silver Foam Dressing is safe for its intended use.

Specifications (All models are presented with both 3mm and 5mm thickness)

Foam or With PU Backing (mm x mm)	PU or Non-woven Adhesive Backing (mm x mm)
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
120×100	150×150(100×100)
120×120	180×180(110×110)
150×100	
150×150	
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in sealed, cool and dry place and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture

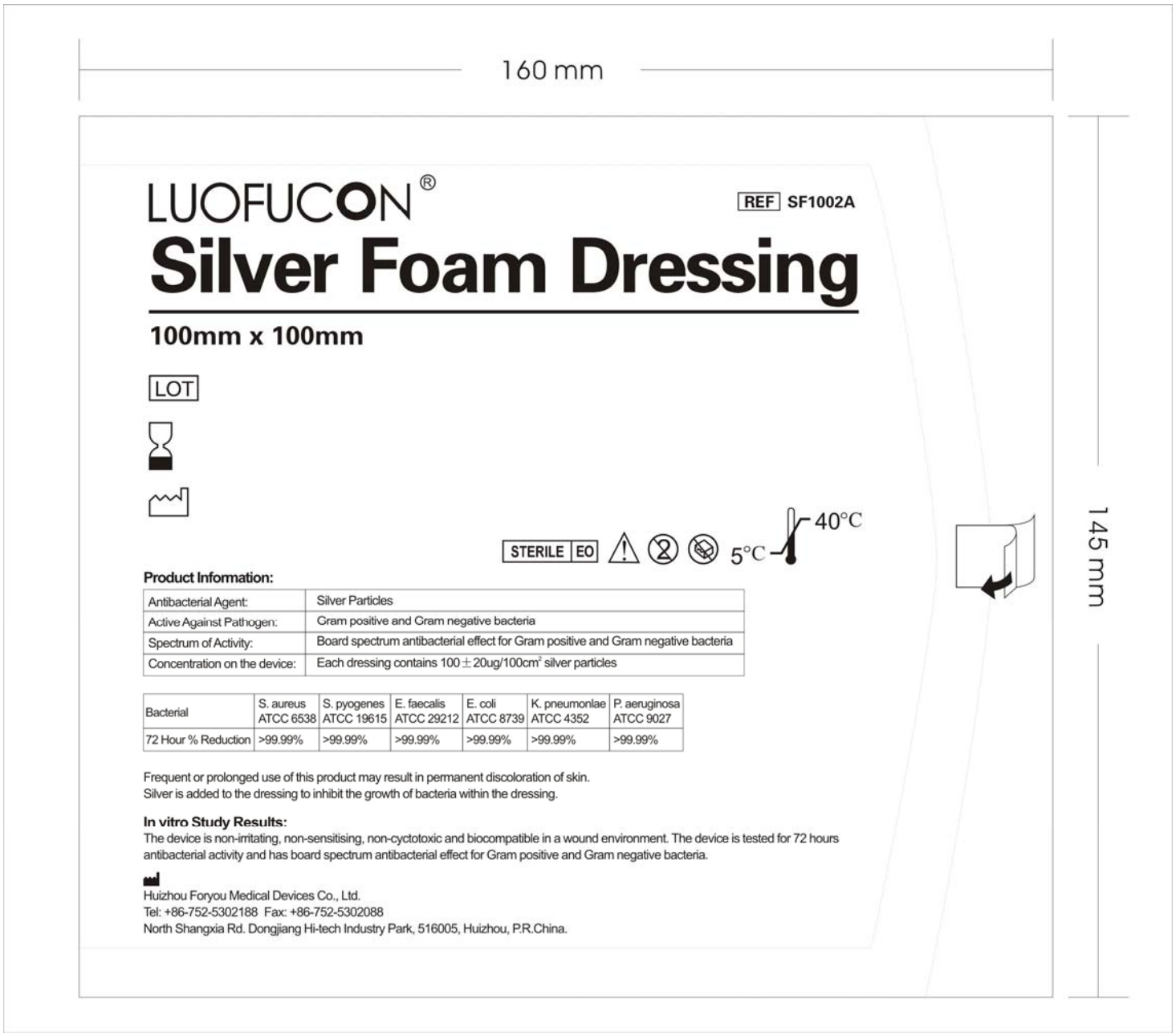
Manufacturer: Huizhou Foryou Medical Devices Co.,Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger



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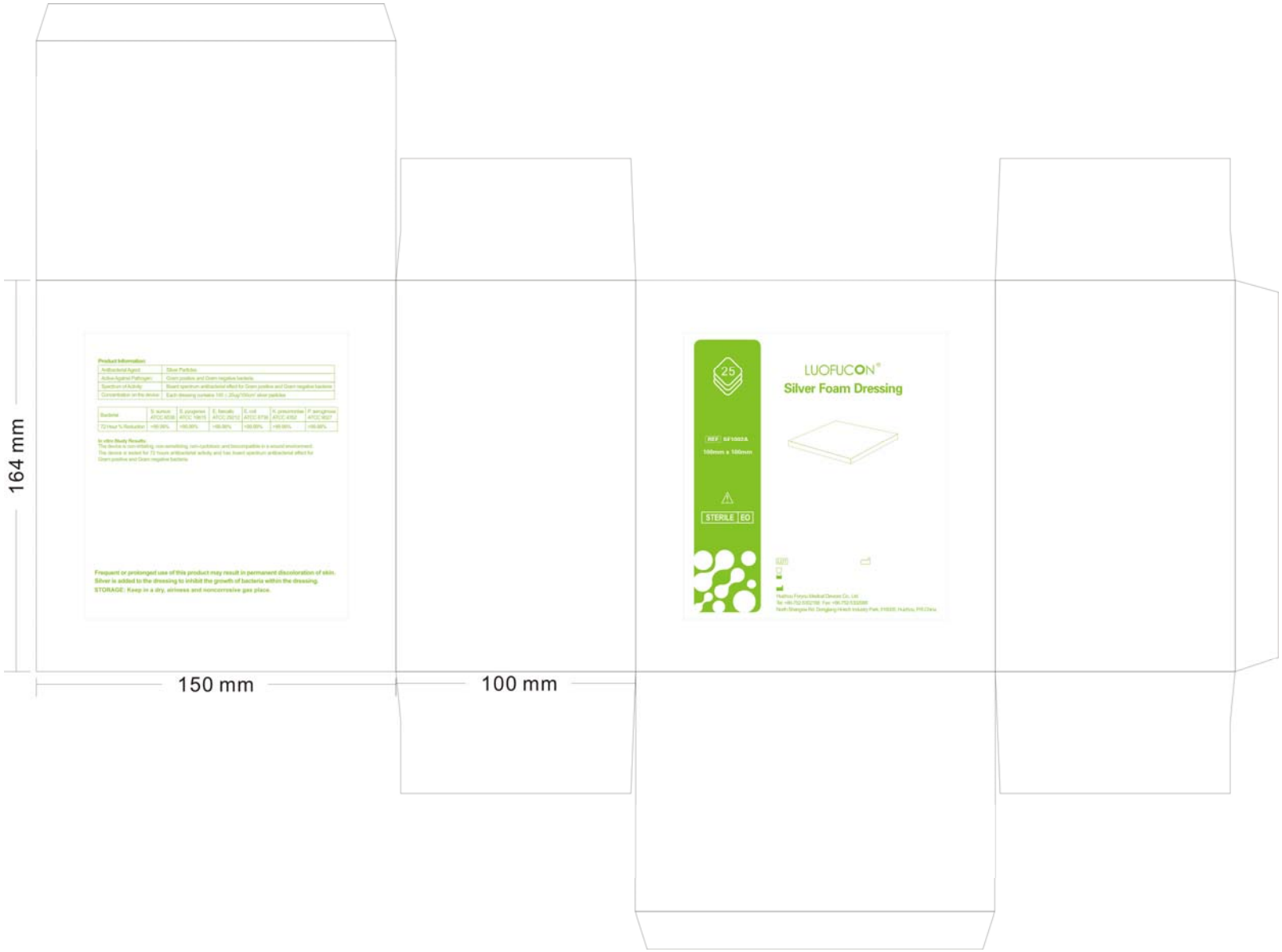
13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

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Section 13: Labeling: Prescription



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Zoom in on left side:

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogen:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 100±20ug/100cm^2 silver particles

Bacterial	S. aureus ATCC 6538	S. pyogenes ATCC 19615	E. faecalis ATCC 29212	E. coli ATCC 8739	K. pneumonlae ATCC 4352	P. aeruginosa ATCC 9027
72 Hour % Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

In vitro Study Results:
The device is non-irritating, non-sensitising, non-cyctotoxic and biocompatible in a wound environment.
The device is tested for 72 hours antibacterial activity and has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Frequent or prolonged use of this product may result in permanent discoloration of skin.
Silver is added to the dressing to inhibit the growth of bacteria within the dressing.
STORAGE: Keep in a dry, airiness and noncorrosive gas place.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zoom in on right side:



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Section 15: Biocompatibility

This section contains the following information

15.1 Cytotoxicity 2
15.1.1 Reference of Standard 3
15.1.2 Experimental 4
15.1.3 Results and Conclusion: 5
15.2 Sensitization Test 6
15.2.1 Reference of Standard 6
15.2.2 Experimental 7
15.2.3 Results and Conclusions: 9
15.3 Irritation Test 10
15.3.1 Reference of Standard 10
15.3.2 Experimental 11
15.3.3 Results and Discussions: 11
15.4 Systematic Toxicity 13
15.4.1 Reference of Standard 13
15.4.2 Experimental 14
15.4.3 Results and Discussions: 14

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Luofucon Silver Foam Dressing is used for the antibacterial and wound care purpose. Based on Table A.1 of ISO 10993-1, it is categorized as surface devices for bleached or compromised surface with prolonged duration. Cytotoxicity, sensitization, and irritation are needed for these devices. These tests are performed in accordance to ISO 10993-5 and ISO 10993-10. We also voluntarily added acute systematic toxicity test, which was performed per ISO 10993-11.

Table below listed the chemical composition of each layer and their patient contact information.

Variant	Variant	Layers	Chemical Composition	Function
First Variant	Basic Model	Polyurethane Foam	Polyurethane	Wound Contact
Second Variant	Non-Adhesive Backing	Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact
Third variant	PU/PET Adhesive Backing	Adhesive	2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid in ethyl acetate/ alcohol	Skin contact /Non Wound contact
		Poly (ethylene terephthalate) Film	Poly (ethylene terephthalate)	Skin contact /Non Wound contact
		Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact
Fourth Variant	PU/Non-Woven Adhesive Backing	Adhesive	2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid in ethyl acetate/ alcohol	Skin contact /Non Wound contact
		Non Woven Film	viscose rayon & poly (ethylene terephthalate) fibers	Skin contact /Non Wound contact
		Polyurethane Film	Polyurethane	Non Contact
		Polyurethane Foam	Polyurethane	Wound Contact

15.1 Cytotoxicity

Agar diffusion test described in ISO-10993-5:2009 was used to evaluate cytotoxicity of the material

In this test, test articles (polyurethane silver foam dressing, first variant), positive and negative control samples were placed on top of agar in separate dishes. All dishes were incubated under appropriate conditions before the cells were stained with Neutral red. The decolorization zone and the cell lysis were examined using inverted microscope. The

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results demonstrated that there was no cytotoxicity for the test article, Luofucon Silver Foam Dressing.

15.1.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected:

(a) The standard allow the tester to select from performing test on extract of the sample, or performing test on the sample itself (section 4.1 of the standards). We choose to perform test on the sample itself

(b) For the same reason above, section 8.4 of the standard: Test by Indirect Contact (Agar Diffusion) was followed, as a proven and well accepted method for solid material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	Sample and Control Preparation	Yes.
5	Cell lines	Yes
6	Culture medium	Yes
7	Preparation of Cell Stock Culture	Yes
8	Test procedures	Yes. Followed procedures in 8.4.1
9	Test report	Yes
10	Assessment of results	Yes

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11	Annex A-D	N/A

15.1.2 Experimental

Indirect test/Agar diffusion method was used in the determination of cytotoxicity.

More experimental details can be found in test report attached in **Appendix 1** of this submission.

Cell Preparation Procedure:
L-929 Mouse fibroblast cells were proliferated following normal procedures before they were trypsinized, collected, and adjusted to a concentration of 1.3×10^5/mL.

Growth Inhibition Test Procedure:
The liquid nutrient medium from each Peri dish was aspirated and replaced with freshly prepared 2.0 mL agar medium. After the agar medium solidified at room temperature, a 10.0 mm diameter disc portion of the test article was placed symmetrically on agar surface. Similarly, negative and positive control samples were also placed on top of agar. All Peri dishes were incubated at 37 °C in 5% CO_2 for 24 hours.

After incubation, the cells were stained with Neutral Red. The decolorization zone and the cell lysis were examined using inverted microscope.

Positive and Negative Control
High density polyethylene was used as the negative control, MEM medium with 0.5% phenol was used as positive control.

Acceptance Criteria: Reactivity was graded based on Table 2 of ISO-10993-5 (also see table below). Score of negative control should be less than 1. Score of the positive control should be higher than 3. All readings from the test article should be no more than 2 to demonstrate none cytotoxicity.

Table 15.1 Reactivity Grade for Cytotoxicity Test

Grade	Description of the Zone
0	No detectable Zone around or under the sample
1	Some malformed or degenerate cells under the sample
2	Zone limited to area under the sample
3	Zone extends 0.5 to 1.0 cm beyond the sample
4	Zone greater than1 cm in extension from the sample

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15.1.3 Results and Conclusion:

Three replicates were tested for each samples and controls. For all replicated tests, the reactivity grades for positive control, negative control, and sample are 4, 0, and 2, respectively. Based on ISO-10993-5, a numerical grade of greater than 2 (≥3) is considered cytotoxic. The test article, Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing has mild reactivity and in general is considered not toxic.

Table 15.2 Cytotoxicity Test Results

Group	Grade	Reactivity
Positive Control		
(1)	4	Severe
(2)	4	Severe
(3)	4	Severe
Negative Control		
(1)	0	None
(2)	0	None
(3)	0	None
Test Article		
(1)	2	Mild
(2)	2	Mild
(3)	2	Mild

The negative and positive control samples meet the requirement specified in acceptance criteria.

The test report (SDWH 2012-22572) can be found in **Appendix 1** of this submission.

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15.2 Sensitization Test

In selecting a new material for human contact in medical applications, it is important to ensure that the material does not stimulate the immune system to produce allergic response. This effect can be evaluated using procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". The maximization method was used.

15.2.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 7 of the standard: Delayed hypersensitivity tests. There are two most commonly used methods for delayed hypersensitivity. Maximization test was selected based on the nature and application of our materials. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes

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5	Pretest considerations	Yes
6	Irritation tests	Will be discussed in Section 15.3. of this submission
7	Sensitization tests	Yes. Note: There are two most commonly used methods for delayed hypersensitivity. The maximization was selected based on the nature and application of our material. The maximization test is preferred for single chemicals. Buehler method is better suited for composite material.
8	Key factors in the interpretation of test results	Yes

15.2.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.
Test article used was polyurethane silver foam dressing, first variant.

Number of Animals: Twenty test animals (ten for sesame oil and ten for 0.9% sodium chloride), five positive control animals, and ten negative control animals (five for sesame oil and five for 0.9% sodium chloride), each weighing 300-500 grams.

Extraction Condition:
The test article was extracted with sesame oil (as non-polar extract) and 0.9% sodium chloride (as polar extract), respectively, in the volume of $3cm^2$/mL. The extractions were performed at 37 °C for 72 hours.

Control Solutions:
Both sesame oil and 0.9% sodium chloride were used as negative control.
10 mg/mL 2,4 Dinitrofluorobenzene (DNFB) in acetone was used as positive control.

Intradermal Induction Phase
A pair of 0.1 ml intradermal injections were made of each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent (sesame oil or 0.9% sodium chloride).

Site B: The test sample (undiluted extract); negative control animals were injected with the chosen solvent alone (sesame oil for non-polar extract or 0.9% sodium chloride for polar extract); positive control animals were injected with the 10 mg/mL DNFB acetone solution alone.

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Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extract (50 %); the control animals were injected with an emulsion of 50:50 sesame oil or sodium chloride with Freund's complete adjuvant; positive control animals were injected with an emulsion of 50:50 10 mg/mL DNFB acetone solution and Freund's complete adjuvant.

Site A	Site A
Site B	Site B
Site C	Site C

Topical Induction Phase

At 6 days after completion of the intradermal induction phase, the test sample (using the concentration selected for site B) was topically administrated to the intrascapular region of each animal, using a filter paper (approximately 8 cm^2) soaked in the test sample extract, to cover the intradermal injection sites. The area was pretreated with 10 % sodium dodecyl sulfate massaged into the skin 24 h before the filter paper was applied. Filter paper was secured with elastic band. They were removed after 48 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Challenge phase

14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. Filter paper soaked in the test sample extract was administrated by topical application to upper flank of each animal (that areas were not treated during the induction stage). The patch was secured, and removed after 24 h.

Negative control animals were treated similarly, with 0.9% sodium chloride (for polar extract) or sesame oil (for non-polar extract) instead of sample extract. Positive control animals were treated similarly, with the 5 mg/mL DNFB in acetone instead of sample extract.

Observation of animals

Challenge skin sites of the test and control animals were observed 24 h and 48 h after removal of the dressings. Observations were made with proper lighting.
Skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading for each challenge site and at each time interval.

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Readings were made without knowledge of the treatment. The test results were based on incidence and severity of the sensitization reaction.

Table 15.3: Grading Scale for Sensitization Test

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

15.2.3 Results and Conclusions:

Clinical Observations: None of the animals in the study showed abnormal clinical signs

Main Test Dermal Observations:
No irritations were observed on the test animals and negative control animals during the induction phase, for both sesame oil and 0.9% sodium chloride extracted samples.

The average grade for positive control animals is 2 from both reports SDWH 2013-21069 and SDWH 2013-21070.

None of the test animals challenged with the test article were observed with sensitization response at any time point of the challenge phase, indicating a 0% incidence. The severity was calculated as "0" at each time point, for both sesame oil and 0.9% sodium chloride extracted samples.

Conclusion:
Based on the above results, material used in the Luofucon Silver Foam Dressing/ Luofucon Antibacterial Foam Dressing does not elicit a sensitization response.

The following test reports can be found in **Appendix 1** of this submission.
SDWH 2013-21824 for Sesame Oil and negative control
SDWH 2013-21714 for Sodium Chloride and negative control
SDWH 2013-21069 for positive control
SDWH 2013-21070 for positive control

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15.3 Irritation Test

The irritation test was conducted following procedures described in ISO-10993-10:2010 Standard, "Biological Evaluation of medical Devices", Part 10 – Tests for Irritation and Delayed Type Hypersensitivity". Human test was not conducted, as our products are made of solid material, thus don't have a high human exposure concentration, such as cosmetics.

15.3.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

(1) In Section 6 of the standard: Irritation Tests. Section 6.4: Human skin irritation test is not performed. Human tests usually are performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Terms and definitions	N/A
4	General principles, step-wise approach	Yes
5	Pretest considerations	Yes
6	Irritation tests	Yes. Note: Section 6.4: Human skin irritation test is not performed. Human tests usually are

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		performed for chemicals that human exposure is high (cosmetics etc). Our material is not in this category.
7	Sensitization tests	Discussed in Section 15.2 of this submission
8	Key factors in the interpretation of test results	Yes

15.3.2 Experimental

Test articles (polyurethane silver foam dressing, first variant) and controls were cut into pieces in the size of 2.5 cm x 2.5 cm.

Only animals with healthy skin were used. 4 sites were designated on each rabbit, with 2 sites on each side of the back, for test and control purpose, respectively. Total three animals were used.

Test material and control were applied directly to the shaved skin of three adult New Zealand White rabbits. After minimum four hours exposure, the patches were removed. Observations for skin irritations were conducted after 1, 24, 48, and 72 hours. The scores were totaled and averaged for the test article and negative control. The primary irritation index was then calculated.

Table 15.4: Grading Scores System Used in Irritation Test

Response category	Comparative Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2-4.9
Severe	5-8

15.3.3 Results and Discussions:

The results are summarized in the table below.

Table 15.5: Summary of Irritation Test Results

Sample	Test Article	Negative Control	Positive Control
1 hour	0.0	0.0	2
24 hours	0.0	0.0	3
48 hours	0.0	0.0	3
72 hours	0.0	0.0	2

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The mean scores for both the test article and negative control are 0 for 1, 24, 48, and 72 hours. Test article does not induce irritation to skin.
The mean scores for positive control are 2, 3, 3, 2 for 1, 24, 48, and 72 hours.

The test report SDWH 2013-21715 for test article and negative control, and test report SDWH 2013-20111 for positive control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.4 Systematic Toxicity

The acute systematic toxicity test was conducted following procedures described in ISO 10993-11:2006 Standard, "Biological Evaluation of medical Devices", Part 11 – Tests for Systematic Toxicity". The acute systematic toxicity was evaluated by the intraperitoneal injection of the extraction solution at 50 mL/kg. The symptom of toxicity and weight growth of test mice were observed and recorded daily. The results demonstrated the lack of systematic toxicity of the test article.

15.4.1 Reference of Standard

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: Yes

In Section 6 of the standard: Acute systematic toxicity by intraperitoneal application described in section 6.5.5. was followed

Any requirements that were not applicable to the device: Section 6.6 (Subacute systematic toxicity), Section 6.7 (Subchronic systematic toxicity), Section 6.8 (Chronic toxicity and carcinogenicity), and Section 7 (Pyrogenicity).

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Test Center of Sanitation and Environmental Technical Institute (Soochow University), 199 Ren'ai Road, Soochow Industrial Park, Suzhou, Jiangsu Province, China. Tel: 011-86-512-65880038

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	N/A
3	Definitions	N/A
4	Test Sample Requirements and Recommendations	Yes
5	Method for Extraction from Medical devices	Yes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6	Selection of Test Procedures for Systematic Toxicity	Yes. Note: Acute Systematic Toxicity described Section 6.5.5 was followed.
7	Selection of Test Procedures for Pyrogenicity	Not performed
8	Assessment of Results	Yes
9	Test report	Yes

15.4.2 Experimental

Greater details of test procedure can be found in the attached Test Report in the Appendix 1.

Test article used was polyurethane silver foam dressing, first variant.

The test article was extracted with sesame oil or saline (0.9% sodium chloride) in the volume of 30 cm^2/10 mL. The extraction was at 37 °C for 72 hours. The sample was completely dissolved as clear solution.

Sesame oil or saline was used as control solution.

Twenty mice were randomly divided into four groups: five mice for sesame oil test group, five mice for saline test group, five mice for sesame oil control group, and five mice for saline control group. Sample extract or control solution (saline) was administered by intraperitoneal injection at a dose of 50 mL/kg. The instant response of each mouse was observed after injection. Furthermore, monitor and record the status of the test and control animals daily for three days.

15.4.3 Results and Discussions:

Acceptance Criteria:
Within the 72 hours of observation period, the toxicosis response of the test group is no greater than the control group.

Results and Discussions
Within the monitoring period of 4, 24, 46, and 72 hours, the toxicosis response of the test group was no greater than the control group for both Saline and Sesame Oil groups. In addition, weight continued to increase for both the test and control group animals.

Conclusions
The test material showed no sign of acute systematic toxicity.

The test reports (SDWH 2013-21825, SDWH 2013-21716) for test article and negative control can be found in **Appendix 1** of this submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA CDRH DMC
JAN 14 2015
Received

K141619/S2

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S002, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

"With regards to your intended use:

a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary. "

Response to FDA Comment 1:

1-CD

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The description, labeling, 510K Summary, and Indications for Use has been revised according to FDA suggestions.

FDA Comment 2:

You have provided a predicate device which also contains silver. In your submission, you state that your device has "relatively low silver release" "compared to other products in the market." However, you have not compared the differences, if any, in silver content between your device and your predicate device. If there is a difference in silver content, this may represent a meaningful difference in the technological characteristics of your device. Please discuss any differences in silver content and, if differences exist, please provide a justification for the increase in silver content. This justification may be in the form of a predicate device which contains the same or greater silver content in the same form (i.e., metallic silver). Please also include an assessment of the toxicological risk of silver in your device, including the potential for toxicity given the potential maximum dose, NOAEL, LOAEL, LD50, etc.

Response to FDA Comment 2:

(1) The discussion of differences in silver content has been added to "Section 12: Substantial Equivalency Discussions" in details, as well as to "Section 05: 510K Summary" in less details.
(2) The discussion of toxicological risks has been added to Section 11.7

FDA Comment 3:

You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.
b. We suggest providing, for each reagent, known published toxicological information.
c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits

Response to FDA Comment 3:

(a) COA and MSDS are added in this supplemental submission
(b) Known published toxicological information are added and discussed in Section 11.7
(c) Quantitative analytical evaluation, including method and detection limit are added to Section 11.7

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Comment 4:

You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

Response to FDA Comment 4:

(a) Results for three different lots, both initial and ages samples, have been added to Section 14 and Section 18
(b) Full test reports have been included in this supplemental submission
(c) Justification has been added following each test in Section 18.
(d) Silver release test has been re-performed following FDA suggestions. The results are summarized in Section 18.8. Test report is included in this supplemental.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Comment 5:

With regards to your antibacterial activity testing:

a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Response to FDA Comment 5:

(a) Clarification has been added to Section 18.6, 3rd paragraph, to clarify "This communication was NOT related to this subject device, but was an FDA general advice on conducting antibacterial testing on any type of antibacterial dressing." FDA email is included in this supplemental submission for your reference.
(b) Summary and labeling have been revised
(c) The information for initial and two year time points has been added to Section 14. Test reports are included in this supplemental submission.
(d) Rational for choose method 1 in calculation has been added to Section 18.6.4
(e) Test report has been revised with clear step (Section 10 of the report) and included in this supplemental submission. Please also see test methodology in the first paragraph of Section 18.6.2.
(f) The confusing parts have been removed from the revised antibacterial test report.
(g) A discussion of this reduction has been added to Section 18.6.4

FDA Comment 6:

With regard to your shelf life:

a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

Response to FDA Comment 6:

(a) Added to Section 14
(b) Test reports has been included in this supplemental submission

FDA Comment 7:

You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

Response to FDA Comment 7:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Release criteria for each variants are added to Section 11.3. For Variants 2, 3,4, there is only additional size criteria and criteria for adhesive strength. Test results for adhesive strength are provided in Section 18.9

FDA Comment 8:

With regards to your labeling:

a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

b. Per the discussion above regarding the role of silver, we believe it is important to emphasize that silver is present only as a preservative for the dressing. Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

c. You state in your User Manual that the device maintains a moist environment "to accelerate healing process." This statement implies that the dressing actively promotes wound healing, which we believe to be a new intended use of this device. We would therefore require that this statement be substantiated by clinical data as part of a PMA submission for a Class III device. Accordingly, please remove this statement.

d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However, you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

e. You present an "In vitro Study Results" section in your package labeling that details the biocompatibility and antibacterial effectiveness testing that has been performed on your device. In addition, your Instructions for Use contains an "Adverse Reactions" section that similarly discusses your biocompatibility testing. However, we believe this text implies that additional performance testing has been conducted beyond biocompatibility and performance testing needed for 510(k) clearance when such testing has not been performed. Therefore, please remove this section.
f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.
g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."
h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.
i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

Response to FDA Comment 8:

Labeling has been revised to address all the above FDA concerns

List of Documents included in this supplemental submission:

001_Response to K141619 Deficiency
002_Section 04_Indications for Use
003_Section 05_510k Summary Re2
004_Section 11_Device Description RE2
005_Section 12_Substantial Equivalence Discussion RE
006_Section 13_Labeling RE2
007_Section 14_Steriliy and Shelf Life Re
008_Section 18_Performance_Testing_BENCH RE
009_COA of AMPTS
010_COA of MTES
011_MSDS of Silver Solution
012_MSDS of AMPTS
013_MSDS of MTES
014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003
017_Test Report on Total Silver Aging Samples
018_Test Report on Silver Release Profile

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

019_Revised Report on Antibacterial Testing
020_Antibacterial Test Report for Control Samples (No Silver)
021_Anticle on toxicity of silver compound
022_Email Communication with FDA

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen Charles Shen

Charles Shen, Official Correspondent
Date: January 10, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S002, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

"With regards to your intended use:

a. You state in your device description that the dressing will protect the wound "from growth of a broad spectrum of bacterial or microorganisms" and that foam dressings are used "in the control of bacterial growth in wounds." These statements imply a chemical action in the wound to reduce infection. Claims regarding silver should be limited to its role as a preservative for the dressing material. Any claims beyond a function within the dressing may be consistent with the definition of a Drug and could be reviewed by our Center for Drug Evaluation and Research (CDER). Accordingly, please remove these statements from your device description. In addition, please clarify the role of silver as a preservative in your 510(k) Summary and your labeling. You may wish to also add a statement regarding silver's preservative function to your Indications for Use.

b. You state in your 510(k) Summary and in your device description that "odour reduction results from the antibacterial effect in the dressing." However, this statement is not supported by your predicate device, nor is it supported by the data you have provided. Please provide a mechanism of action for this claim and substantiate this claim with performance testing. Alternatively, please remove this statement from your device description and 510(k) Summary. "

Response to FDA Comment 1:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The description, labeling, 510K Summary, and Indications for Use has been revised according to FDA suggestions.

FDA Comment 2:

You have provided a predicate device which also contains silver. In your submission, you state that your device has "relatively low silver release" "compared to other products in the market." However, you have not compared the differences, if any, in silver content between your device and your predicate device. If there is a difference in silver content, this may represent a meaningful difference in the technological characteristics of your device. Please discuss any differences in silver content and, if differences exist, please provide a justification for the increase in silver content. This justification may be in the form of a predicate device which contains the same or greater silver content in the same form (i.e., metallic silver). Please also include an assessment of the toxicological risk of silver in your device, including the potential for toxicity given the potential maximum dose, NOAEL, LOAEL, LD50, etc.

Response to FDA Comment 2:

(1) The discussion of differences in silver content has been added to "Section 12: Substantial Equivalency Discussions" in details, as well as to "Section 05: 510K Summary" in less details.
(2) The discussion of toxicological risks has been added to Section 11.7

FDA Comment 3:

You provided a list of the chemicals involved in the encapsulation of silver particles in the foam. However, this information is incomplete. We require more detailed information to understand possible safety concerns regarding the chemical composition and processing of your device. Therefore, please address the following issues:

a. We suggest including, for each reagent and component, a certificate of analysis as well as the MSDS.
b. We suggest providing, for each reagent, known published toxicological information.
c. Finally, in consideration of a reagent's toxicity, we recommend that you provide the quantitative analytical evaluation of the foam for any residual reagents, including methods and detection limits

Response to FDA Comment 3:

(a) COA and MSDS are added in this supplemental submission
(b) Known published toxicological information are added and discussed in Section 11.7
(c) Quantitative analytical evaluation, including method and detection limit are added to Section 11.7

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Comment 4:

You have provided performance tests characterizing the density, absorbency, loss on drying, pH, silver content, antibacterial activity, and silver leachability of your device. You have also provided shelf life testing that conducts performance testing on aged devices. Please address the following issues:

a. In most of the aforementioned tests, only one lot was evaluated; in some cases, only one sample was tested. This appears to extend to your shelf life testing, in which only one lot was aged. As these tests were conducted in part to verify your product specifications, release criteria, and shelf life, evaluating one sample or one lot to represent the potential variation of product performance across all your variants and production batches is inadequate. Therefore, please provide the results of testing of three different lots of your devices. Please also provide the results of testing of three real-time aged lots of your device as well.

b. You provided summary reports for your tests. For some simple testing (density, for example), what you provided is adequate. However, for other testing, including but not limited to silver content, silver leachability, and in all testing to substantiate your stated shelf life, the full test reports are not provided. Without the method as enumerated in the full test report, we cannot determine the adequacy of the test results because the method of testing is unclear. Thus, for each test, please provide a full test report that includes test methodology, protocol, raw data, summarized results, and all acceptance criteria. This information enables us to verify the results of your testing.

c. In almost all of your testing, the 100 x 100 x 3 mm foam dressing (first variant) was tested. However, none of the other variants of your device were tested. Moreover, it is unclear how the testing of the foam dressing you provided adequately applies to the other variants of your device, some of which contain additional components such as a nonwoven layer and adhesives. Therefore, for each test or group of tests, please provide justification for the 100 x 100 x 3 mm dressing as the representative model for all the variants of your device. This information will enable your testing to be applicable to your other device models.

d. According to your performance testing as provided, the 100 x 100 x 3 mm foam dressing should be able to absorb approximately 45 mL of simulated wound fluid. However, in your silver leachability study, only 20 mL was used. 20 mL would be insufficient to contact all the silver in the dressing and would thus not represent the maximum amount of potential leached silver. Therefore, please explain why only 20 mL was used. If 20 mL does not saturate the foam dressing, please provide the results of silver leachability testing with an excess amount of simulated wound fluid.

Response to FDA Comment 4:

(a) Results for three different lots, both initial and ages samples, have been added to Section 14 and Section 18
(b) Full test reports have been included in this supplemental submission
(c) Justification has been added following each test in Section 18.
(d) Silver release test has been re-performed following FDA suggestions. The results are summarized in Section 18.8. Test report is included in this supplemental.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Comment 5:

With regards to your antibacterial activity testing:

a. You stated in your submission that there were no prior submissions related to this submission. However, in your antibacterial activity test summary, you stated that you "used the procedure FDA recommended during our communication with FDA." This statement indicates that you discussed this device at some point with us in the past. Please provide the pre-submission number or file number for your previous discussion with the FDA.

b. You state the dressing should be protected from a "broad spectrum of bacterial or microorganisms." However, you have only tested gram positive and gram negative bacteria. We interpret the term "microorganisms" as encompassing fungi and yeast. Therefore, please revise your Summary (and any labeling as needed) to state that the device has antibacterial effects within the dressing. If you instead wish to claim antimicrobial effectiveness, you should provide a complete test report that demonstrates your device's effectiveness against fungi and yeast.

c. You stated that antibacterial testing was tested at time zero and at 1 year for devices undergoing real-time aging. However, reports for this testing were not located in your submission. If samples were tested at these time points, please provide this data so the antibacterial effect can be evaluated at each time point.

d. You reference the use of the AATCC Test Method 100-2004: "Antibacterial Finishes on Textile Materials: Assessment of". The standard calls for one gram positive (Staphylococcus aureus) and one gram negative (Klebsiella pneumoniae) and for three different methods for calculating the log reduction of bacteria after antimicrobial testing. However, you did not provide a rationale as to why the first method was chosen. Please provide a rationale for your choice, and please provide a discussion of whether results would be similar if one of the other two methods were to be used. Please be advised that FDA does not recognize this standard.

e. You stated that only two modifications to the AATCC 100-2004 testing method were made. However, there are more than two modifications to the method, and the protocol itself is confusing and not easily understood. Please explain the test methodology behind your antimicrobial testing protocol, and provide a revised protocol (with clear steps) that clarifies what and how the testing was performed on the finished device. Please be advised that this standard is not recognized by FDA.

f. You tested multiple sample groups with varying species of bacteria; however, the groups are poorly labeled and thus distinguishing each sample group is difficult. Please clearly identify and distinguish the sample groups tested in your antibacterial effectiveness testing.

g. You inoculated untreated devices with the six bacteria you specified. While five species increased by tenfold, Streptococcus pyogenes decreased by over 30%. Please provide an explanation for the unexpected reduction of the bacterial log for this species.

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Response to FDA Comment 5:

(a) Clarification has been added to Section 18.6, 3rd paragraph, to clarify "This communication was NOT related to this subject device, but was an FDA general advice on conducting antibacterial testing on any type of antibacterial dressing." FDA email is included in this supplemental submission for your reference.
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(c) The information for initial and two year time points has been added to Section 14. Test reports are included in this supplemental submission.
(d) Rational for choose method 1 in calculation has been added to Section 18.6.4
(e) Test report has been revised with clear step (Section 10 of the report) and included in this supplemental submission. Please also see test methodology in the first paragraph of Section 18.6.2.
(f) The confusing parts have been removed from the revised antibacterial test report.
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FDA Comment 6:

With regard to your shelf life:

a. You state in your shelf life testing that silver content was not measured as "silver content is not expected to change over the course of time." We do not agree with this rationale and believe that silver content may change over the course of real-time aging. Therefore, please provide the results of measurement of the silver content of aged devices.

b. You state that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided. Please provide the test reports for your package integrity testing.

Response to FDA Comment 6:

(a) Added to Section 14
(b) Test reports has been included in this supplemental submission

FDA Comment 7:

You provided release criteria for the first variant of your device, the foam dressing. However, it is unclear if other release criteria exist for the second, third, and fourth variants. Please clarify if additional release criteria for the other, more complex variants of your device exist. If such criteria exist, please provide the results of testing of multiple batches of the device to verify that lot specifications can be reliably met.

Response to FDA Comment 7:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Release criteria for each variants are added to Section 11.3. For Variants 2, 3,4, there is only additional size criteria and criteria for adhesive strength. Test results for adhesive strength are provided in Section 18.9

FDA Comment 8:

With regards to your labeling:

a. You state in your user manual that your device "can restrain the bacteria growing and reduce infection." This statement regarding the reduction of infection represents a new intended use for this device. Additionally, this statement is a drug claim (as the mechanism would presumably be through the release of silver ions) and could lead to the transfer of review jurisdiction to CDER. Therefore, please remove this statement and indicate that the silver is present as a preservative to inhibit bacterial colonization within the dressing.

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d. You stated in your labeling that your device demonstrates antibacterial activity for 3 days. You also state in your Instructions for Use that the "dressing may be left in place for up to 7 days." This statement implies that the antibacterial effect within your product may also last for 7 days, when in fact the antibacterial effect only lasts for 3 days. Finally, you also stated that your device "is intended for short-term use up to 28 days." However, you also state in your Warnings section of your Instructions for Use that "frequent or prolonged use of this product may result in permanent discoloration of skin." It is unclear how use of the product for 28 days would not be characterized as "frequent or prolonged use." Therefore, please address the following issues:

i. Please clarify whether the device is intended to be used after the period of antibacterial effectiveness for the dressing has ended. If so, please conduct a clinical risk analysis to determine whether leaving your device on the wound can pose additional clinical risk to the wound site. Please assess this for each wound type in your indications as the risks may be different for different wound types. Alternatively, please revise your labeling to limit its use to 3 days.

ii. Please clarify whether you intend for the device to be used continuously for 28 days or whether you intend to change the device at regular periods but not expose the patient to your device for more than 28 days. If continuous use is expected, please provide data to demonstrate that 28 days of continuous use is safe for managing wounds and that the encapsulated silver provides antibacterial effectiveness for the dressing

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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over that time. If multiple dressing changes are expected, please provide a toxicological justification for repeated patient exposure to silver as requested in Deficiency 2.

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f. For each dressing size, please state the total maximum amount of silver in the dressing on the package labeling.
g. Please remove statements of "% reduction" from your package labeling. Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria: (mention the names of each strain tested)."
h. Please include the materials of composition of the device on all labeling, including the components of the additional layers for a particular variant.
i. Please add a statement to the immediate package labeling to see the User Manual for complete Instructions for Use.

Response to FDA Comment 8:

Labeling has been revised to address all the above FDA concerns

List of Documents included in this supplemental submission:

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003_Section 05_510k Summary Re2
004_Section 11_Device Description RE2
005_Section 12_Substantial Equivalence Discussion RE
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012_MSDS of AMPTS
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015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003
017_Test Report on Total Silver Aging Samples
018_Test Report on Silver Release Profile

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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019_Revised Report on Antibacterial Testing
020_Antibacterial Test Report for Control Samples (No Silver)
021_Anticle on toxicity of silver compound
022_Email Communication with FDA

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles shen

Charles Shen, Official Correspondent
Date: January 10, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141619

Device Name

Luofucon Silver Foam Dressing

Indications for Use *(Describe)*

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: May 15, 2014

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

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The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

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Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

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Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver Foam dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 5: 510(K) Summary: Prescription

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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Section 11: Device Description

This section contains the following information

11.1 Design Requirements: 2
11.2 General Description and Pictures: 2
11.3 Specifications: 8
11.4 Summary of Test Results 11
11.5 List of All Materials Used 12
11.6 Manufacturing Process 13
11.7 Discussion of Toxicological Properties of Reagents Used in Manufacture Process 15
11.8 Silver Compound Used in the Products and Silver Particle Size 16
11.9 Bonding Between Silver Particles and Silver Leachability 17
11.10 Antimicrobial Activity Spectrum (Profile) 22
11.11 Minimum Effective Concentration 22
11.12 Likely Silver Antibacterial Mechanism 23

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

11.1 Design Requirements:

Silver foam dressing is used in the wound protection and in the control of bacterial growth in wounds. Following are some of factors being considered when our silver foam wound dressing is designed:

(1) The dressing should be able to absorb wound fluid.
(2) The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms.
(3) The materials used in the dressing should not be toxic, should not be irritating, and should not cause any immune response.
(4) The materials used in the dressing are from reliable vendor and of high and consistent quality.

Based on the above requirement, our products have the following technical characteristics:

11.2 General Description and Pictures:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

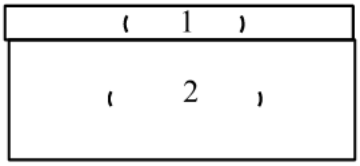
The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2, Table 11.5).

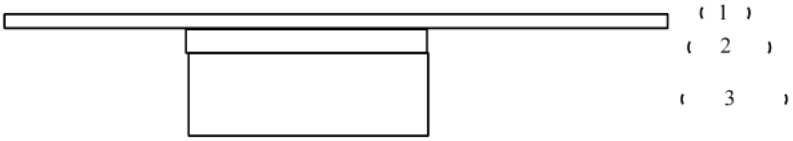
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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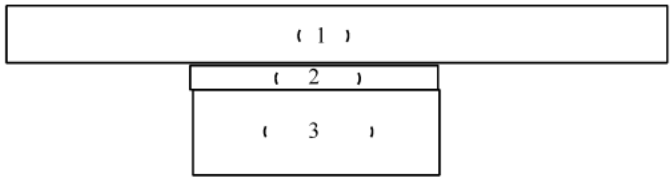
Illustrative drawing of the second variant: (1)) Thin polyurethane backing layer for cosmetic purpose (2) Thick polyurethane wound contacting layer

A third adhesive variant, bordered PU backing with adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.3, Table 11.5).



Illustrative drawing of the third variant: (1) Thin PET layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.4, Table 11.5).



Illustrative drawing of the fourth variant: (1) Non woven layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

For the third and fourth variants, the adhesive is composed of 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

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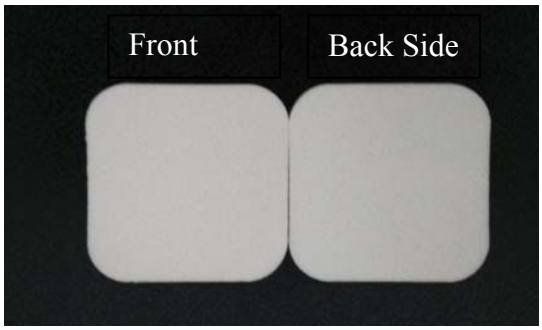
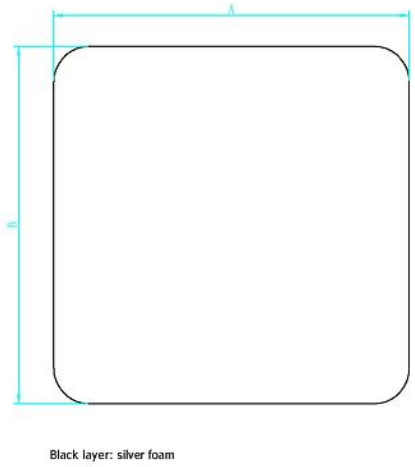
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Section 11: Device Description

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below. Secondary layer information are summarized in Table 11.5.

Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

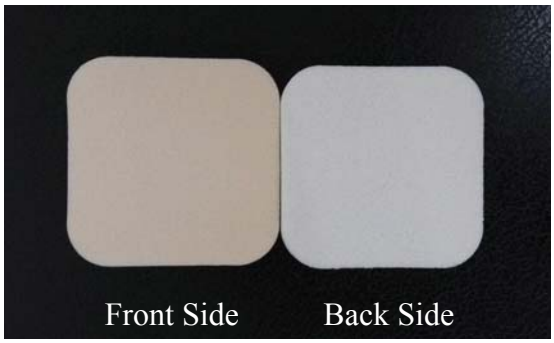
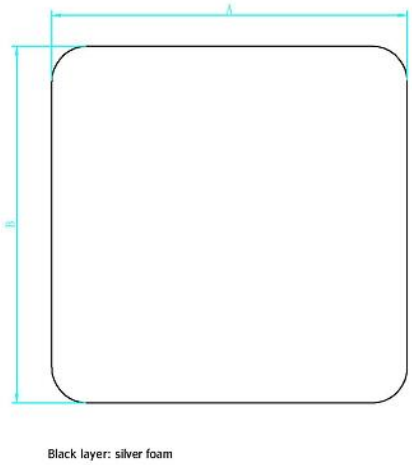
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

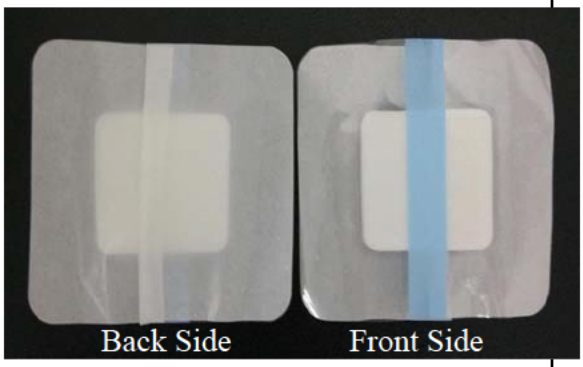
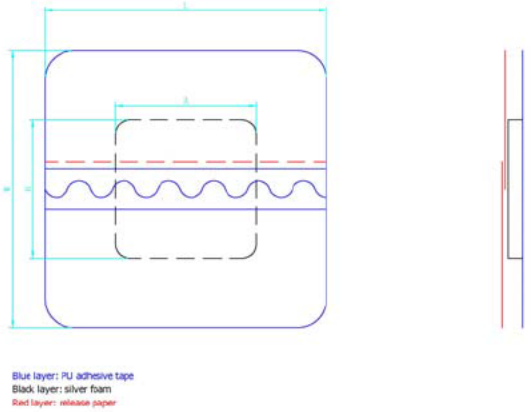
Representative Picture	Drawing
	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
	

Size

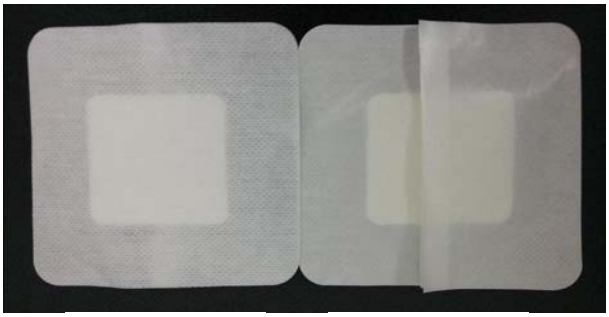
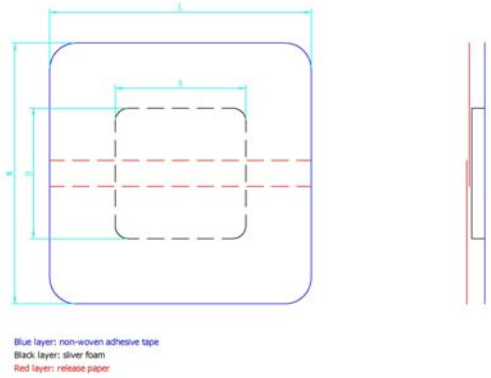
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
 Front Side Back Side	

Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.5: Secondary Layer Information Summary

Variant	Variant	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Packaging information is listed below:

Immediate Packaging: Enforced paper - Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging: Paper Box
Outer Packaging: Corrugated Board Carton

11.3 Specifications:

The specifications are developed to ensure the product is suitable for its intended use. They are developed based on the Design Requirements outlined in Section 11.1.

The physical specifications are shown in Table 11.6 to Table 11.9, for the Variants 1-4. The biological specifications are shown in Table 11.10.

Table 11.6: Physical Specification of Luofucon Silver Foam Dressing, First Variant

Test items	**Specification**	**Test Method [a]**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Density	0.09-0.18 g/cm^3	Internal Method
Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Loss on Drying	≤6%	USP 34 <731> Loss on drying
pH	4.0～9.0	USP 34 <791> pH
Silver Content	3±1 μg/cm^3	Internal Method Adapted from

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.7: Physical Specification of Luofucon Silver Foam Dressing, Second Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method
Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.8: Physical Specification of Luofucon Silver Foam Dressing, Third Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
PET Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
PET Layer	Seal Strength	Shift by less than 2.5 mm	British Pharmacopoeia 1993 Appendix XXH Test 1
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method

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Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

Table 11.9: Physical Specification of Luofucon Silver Foam Dressing, Fourth Variant

Component	**Test items**	**Specification**	**Test Method [a]**
Overall	Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Visual
Skin Contact Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Secondary Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Non Woven Layer	Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Calibrated ruler
Non Woven Layer	Seal Strength	Shift by less than 2.5 mm	British Pharmacopoeia 1993 Appendix XX H Test 1
Skin Contact Layer	Density	0.09-0.18 g/cm^3	Internal Method
Skin Contact Layer	Free Swell Absorption	≥10.0 g/g	EN 13726-1: 2002
Skin Contact Layer	Loss on Drying	≤6%	USP 34 <731> Loss on drying
Skin Contact Layer	pH	4.0～9.0	USP 34 <791> pH
Skin Contact Layer	Silver Content	3±1 μg/cm^3	Internal Method Adapted from
Skin Contact Layer	Antibacterial Activity	> 99.99% for up to three days	AATCC 100: 2004

[a]: Details of the test method are described in *Section 18: Performance Testing: Bench*

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The biological specifications are shown in Table 11.10.

Table 11.10 Biological Specifications for Variants 1-4.

	Requirement	Test Method
Cytotoxicity	No more than grade 2	ISO-10993:5
Skin Irritation	Grade <1.0	ISO-10993:10
Delayed Sensitization	Grade 0 or 1	ISO-10993:10
Acute Systematic Toxicity	No Systematic Toxicity	ISO-10993:11

Details about how the tests are performed are described in *Section 15: Biocompatibility*

11.4 Summary of Test Results

(b) (4)

Exemplary test results for batch S201107001, size 100 mm x 100 mm x 3 mm are presented in Tables 11.11 and 11.12.

Test results of additional lots and additional variants can be found in Section 18.

Table 11.11: Exemplary Physical Test results of Luofucon Silver Foam Dressing (Batch: S201107001, size 100 mm x 100 mm x 3 mm)

Test items	**Specification**	**Test Results**
Appearance	Porous elastomer, clean, odorless, free of damage and stain, uniform thickness, and soft texture.	Conform
Dimension	Deviation ≤ ±5% for length and width; ≤ ±10% for thickness	Conform
Density	0.09-0.18 g/cm^3	0.112 gram/cm^3
Free Swell Absorption	≥10.0 g/g	12.6 g/g
Loss on Drying	≤6%	3.11%
pH	4.0～9.0	4.47

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Silver Content [a]	3±1 µg/cm^3	3.1 µg/cm^3
Antibacterial Activity	> 99.99% for up to three days	> 99.99% for three days for all six bacteria

[a:] Incoming Quality Control

Table 11.12: Exemplary Biological Test results of Luofucon Silver Foam Dressing (Batch S201207003 & S201305001, size 100 mm x 100 mm)

	Requirement	Test Results
Cytotoxicity	No more than grade 2	Grade 2
Skin Irritation	Grade <1.0	Conform
Delayed Sensitization	Grade 0 or 1	Grade 0
Acute Systematic Toxicity	No Systematic Toxicity	Conform

11.5 List of All Materials Used

(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

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(b) (4)

Leachability of silver particles was studied using the following approach. The samples tested are:

LOT	S201207002	S201207003	S201305001
Type	Silver Foam dressing (Variant 3)	Silver Foam Dressing (Variant 1)	Silver Foam Dressing (Variant 1)
Manufacture Date	2012.7.29	2012.7.30	2013.5.2
Size	150×150mm (100×100×5mm)	100×100×5mm	100×100×3mm
Extraction Volume	75 mL	75 mL	45 mL

One piece of silver foam dressing in the different sizes and thickness mentioned in above table was used and immersed in simulated wound fluid under fixed conditions. The fixed condition is the following:

Simulated wound Exudates: 10% porcine serum and 90% phosphate buffer 10 mM, Ph 6.8
Volume of Exudates: 20 mL for the first 24 hours, and for 48, and 72 hours
Extraction temperature: 37 ^{o} C
Sampling time: 24, 48, 72 hours

This test condition represents real conditions of use because simulated wound exudates were used, and 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) daily volume mimics moderate to heavily exuding.

After 24 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 48 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by ICP-MS (Inductively coupled plasma mass spectrometry). Then 45 mL (for 3 mm thickness foam) or 75 mL (for 5 mm thickness foam) of fresh simulated wound fluid was added to immerse the silver dressings under testing.

After 72 hours the dressings were removed, while the simulated wound exudates were filtered. The filtrate was analyzed for silver content by validated internal FAB test procedure.

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The test results are summarized in the Table 18.11 below. Daily Leachable and Total Leachable are the actual detected silver leached from the foam dressings, as the experimental condition above states. % of Total Silver is calculated using a nominal silver amount of 3 μg/ cm^3. Therefore, 100 x 100 x 5 mm foam contains 150 μg silver, and 100 x 100 x 3 mm foam contains 90 μg silver.

The leachables are calculated as both daily leachable, which is the leached silver amount within 24 hour periods, and total leachable, which is the total leached silver amount over the course of the testing.

Table 1: Silver Release Study of LOT S201207002

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (μg)	Daily Release as % of Total Silver[a]	Total Release (μg)	Total Release as % of Total Silver[a]
24	1.0722	75	80.42	53.61%	80.42	53.61%
48	0.3884	75	29.13	19.42%	109.55	73.03%
72	0.1636	75	12.27	8.18%	121.82	81.21%

[a]: 150×150mm (100×100×5mm) silver foam contains about 150μg silver, and was use in the calculation.

Table 2: Silver Release Study of LOT S201207003

Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (μg)	Daily Release as % of Total Silver[b]	Total Release (μg)	Total Release as % of Total Silver[b]
24	1.1108	75	83.31	55.54%	83.31	55.54%
48	0.4057	75	30.43	20.29%	113.74	75.83%
72	0.1871	75	14.03	9.36%	127.77	85.18%

[b]: 100×100×5mm silver foam contains about 150μg silver, and was use in the calculation.

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Table 3: Silver Release Study of LOT S201305001

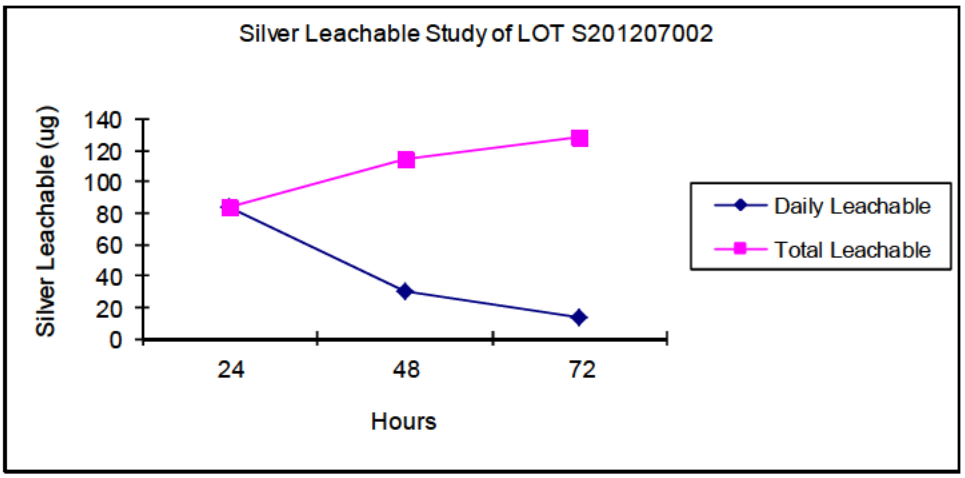
Extraction Hours	Detected Silver Concentration (mg/L)	Exudate Volume (mL)	Daily Release (µg)	Daily Release as % of Total Silver[c]	Total Release (µg)	Total Release as % of Total Silver[c]
24	0.9874	45	44.43	49.37%	44.43	49.37%
48	0.3529	45	15.88	17.65%	60.31	67.02%
72	0.1370	45	6.17	6.85%	66.48	73.87%

[c]: 100×100×3mm silver foam contains about 90µg silver, and was use in the calculation.

Under this simulated condition, LUOFUCON Silver Foam Dressing leaches maximum 55.54% of the total silver during the first 24 hours, and leaches maximum 20.29%, and 9.36% of its total silver during 24-48, and 48-72 hours, respectively. Over the first 72 hours maximum 85.18% of the total silver was leached out.

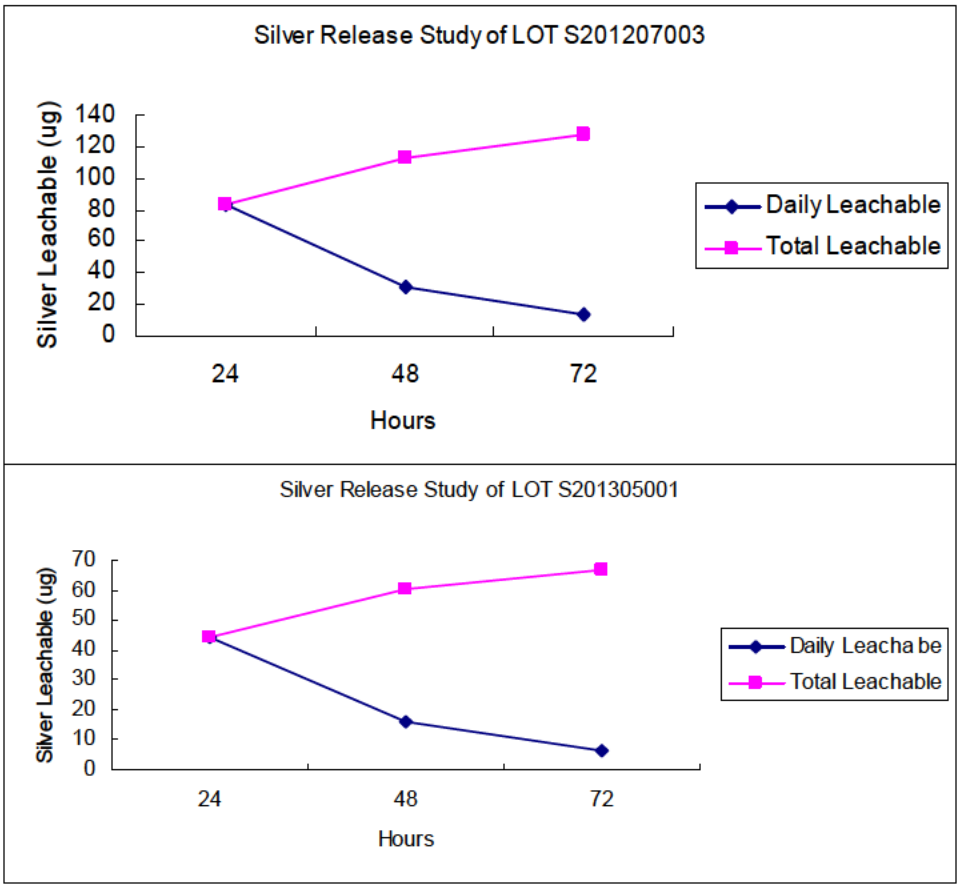
Since the nominal concentration of silver 3±1 µg/cm^3, after three days of recommended usage duration, at least 85.18% of silver is released, equivalent to at least 2.64 µg/cm^3. This number, 2.64 µg/cm^3, will be converted to µg per device and shown in product label as estimated release amount to the patient after device use.

Compared to other products in the market, our silver foam dressing has relatively low silver release, in theory might cause much less skin discoloration effect.



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Details of this experiment can be found in **Section 18**

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11.10 Antimicrobial Activity Spectrum (Profile)

Silver or silver ions have long been known to possess strong inhibitory and bactericide effects as well as a broad spectrum of antimicrobial activities. Unlike the case with antibiotics, there is little current evidence of emerging microbial resistance to silver. This has been discussed in the following book chapter:

> Silver and Its Compounds in Disinfection, Sterilization and Preservation, edited S.S. Block, Lea & Febiger, Philadelphia, p.375 (1983).

Literature references on the broad spectrum of antimicrobial activities of silver have also been extensive, and below are just some of the examples which are far from exclusive:

> Wright JB, Lam K, Burrell RE. Wound management in an era of increasing bacterial antibiotic resistance: a role for topical silver treatment. **Am J Infect Control.** 1998;26(6):572–577.
>
> Percival SL, Bowler PG, Russell D. Bacterial resistance to silver in wound care. **J Hosp Infect.** 2005; 60(1):1–7.

In a more recent example published in **Digest Journal of Nanomaterials and Biostructures,** 2011, Vol. 6, No 1, p. 149 - 154, N. Lkhagvajav et. al. studied the antibacterial activity of a colloidal silver and found it to be effective against a variety of Gram positive, Gram negative bacteria and fungi. The experiments were performed following standard broth microdilution methods described by the NCCLS.

Therefore, the conclusion is well supported that silver is a broad spectrum antibacterial agent.

11.11 Minimum Effective Concentration

Minimum effective concentration is the minimum concentration of the antimicrobial agent on the device that achieves the stated 4-log reduction. MEC is a very important element of device design controls. The MEC testing should be performed under conditions that are consistent with clinical use of the device.

Our determination of this device characteristic was based on the following considerations:

1. The Indication for Use of the device - what pathogens are expected to be encountered? How susceptible in general are those pathogens to the antimicrobial agent included in the final device? In what clinical time frame will the device be expected to exert its stated effect, whatever that is?

2. What amounts of antimicrobial agent will leach off/wear off/ gas off the device during use? What is the use life of the device for an average patient?

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3. How stable is the added antimicrobial agent during the shelf life of the device? Will sufficient antimicrobial agent be left on the device at the end of the stated shelf life to permit device performance equal to that of a new device?

4. Will the level of antimicrobial agent needed to "do the job" which the antimicrobial plus device intends to do result in safety issues?

After careful consideration, we decided to use the following approach. Since the target silver concentration on our device is 3 μg/cm^3, and its effectiveness has been demonstrated in Section 18.7, we have prepared a series of test samples with the silver concentrations range of 1.35, 2.20, and 2.85 μg/ cm^3

The antibacterial effectiveness of each sample was tested using AATCC-100, following the same procedure described in detail in **Section 18.7**, with the exception that only one Gram positive bacteria and one Gram negative bacteria were tested as representative bacteria. Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginaosa (ATCC 9027) have been demonstrated to be the two most difficult bacteria to kill among the six tested, so as the worst case scenario they were chosen to establish the minimum effective concentration.

At 1.35 μg/ cm^3, the dressing achieves 4 log reductions for Pseudomonas aeruginaosa, but only achieves 4 log reduction for Staphylococcus aureus in two out of three replicates. However, at 2.20 μg/ cm^3 or above, the dressing achieves 4 log reductions for both Pseudomonas aeruginaosa and Staphylococcus aureus.

Therefore, the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20ug/cm^3, most likely a little more than 1.35ug/cm^3.
Details of this experiment can be found in **Section 18.8**.

11.12 Likely Silver Antibacterial Mechanism

Like many heavy metals, silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi. However, silver does not have the high toxicity to humans normally associated with these other metals.

Silver Foam Dressing absorbs wound exudate and releases silver in the presence of wound fluid. Silver has long been known for its antibacterial activity, although the exact mechanism is still under debate.

Generally, the antimicrobial properties of silver stem from its ability to form strong molecular bonds with other substances used by bacteria to respire, such as molecules containing sulfur, nitrogen, and oxygen. When the silver forms a complex with these molecules, they are rendered unusable by the bacteria, depriving them of necessary compounds and eventually leading to their death.

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Section 12: Substantial Equivalence Discussion

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

Table 12.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MedliPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same

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Antibacterial Duration	Three days	Three days [a]
Single Use	Yes	Yes
Sterile	Sterile	Sterile

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains about 3μg/cm^3 silver, equivalent to about 27 ppm when the density is about 0.11 g/cm^3. The predicate device contains about 79 ppm silver. According to a recent research (Particle and Fibre Toxicology, 2010, 7:20), the NOEAL and LOEAL of silver are 30 and 125 ppm respectively (Included in this supplemental submission). Therefore the silver content in the subject device is less than the predicate device, and is less than what NOEAL and LOEAL allow. Silver content at this level is not going to raise any safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 12.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 12.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection

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Antibacterial Duration	Three days	Three days [a]

[a]: The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2.

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing. Luofucon Silver Foam Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for three days.

The 510(K) Summary of the predicate device lists effective duration of 5-7 days, however, their promotional material shows the 4 Log reduction of only 3 days. See Appendix 2. Our device has the same antibacterial duration of three days. We have specified in the User Instruction that the dressing may be changed every three days when using our products for antibacterial purpose.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.

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Section 13: Proposed Labeling

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The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

Rx Only
Version: A/0

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure containing silver particles which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. The total maximum amount of silver partilces is 4ug/cm^3. The silver is present as a preservative to inhibit bacterial colonization within the dressing. LUOFUCON® Silver Foam Dressing has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.
The **Silver Foam Dressing with PU Backing** consists of silver foam and breathable polyurethane film for waterproof. The **Bordered Silver Foam Dressing** is silver foam on a PU/PET film or non-woven coated with acrylic adhesive and extends to act as a border adhesive to allow fixation without secondary dressing or fixation bandage.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers(venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns(1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

In Vitro Study Results:
The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment. This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria:

Proven Antibacterial Effectiveness

Bacterial	72 Hour Log Reduction
Staphylococcus aureus (ATCC 6538)	4 Log
Streptococcus pyogenes (ATCC 19615)	4 Log
Enterococcus faecalis (ATCC 29212)	4 Log
Escherlchia coli (ATCC 8739)	4 Log
Klesiella pneumonlae (ATCC 4352)	4 Log
Pseudomonas aeruginosa (ATCC 9027)	4 Log

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Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. The dressing should be left on the skin for no more than three days.

Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Specifications (Including 3mm and 5mm)

Foam or With PU Backing	PU or Non-woven Adhesive
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
125×100	150×150(100×100)
150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

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13.2 Pouch Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

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Variant 1:



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Variant 2:



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Variant 3:



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Variant 4:



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13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

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Variant 1



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Variant 2:



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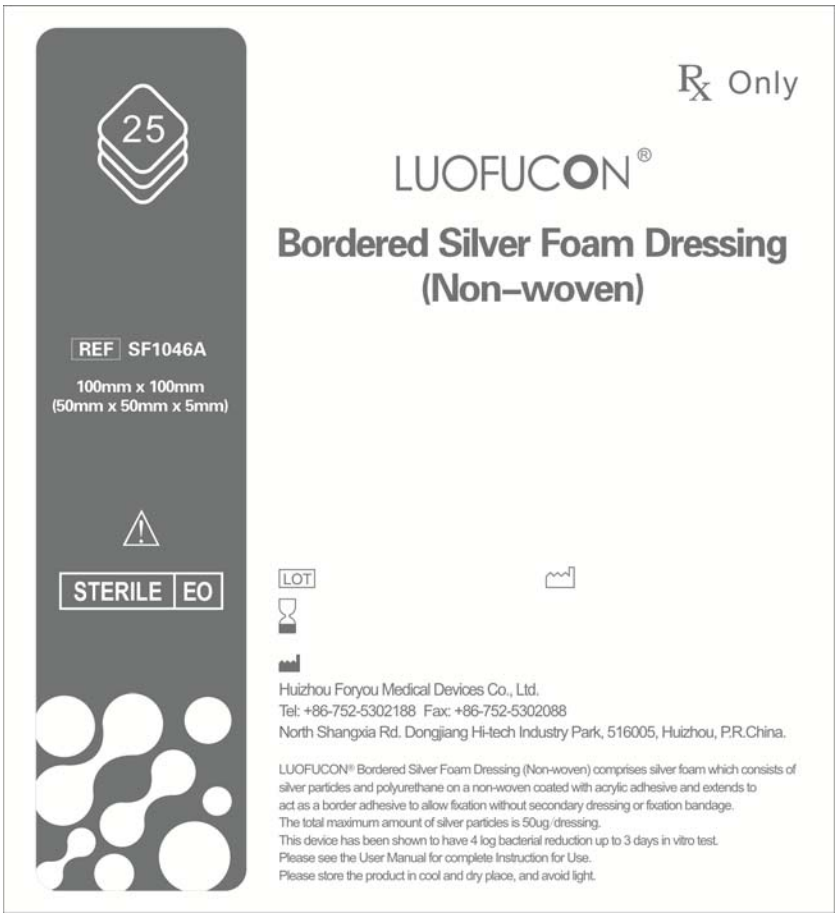
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Section 14: Sterility and Shelf Life

Luofucon Silver Foam Dressing is sold directly to users after EtO sterilization validation to ISO 11135-1:2007, the sterilization method to be used is ethylene oxide with overkill approach. The details are the following:

14.1 Sterility Validation

The ethylene oxide method used to sterilize our "Luofucon Silver Foam Dressing" was validated following ISO 11135-1:2007. The method validation report can be found in **Appendix 1.**

Foam dressing without silver deposition was used to validate the procedure. Because of the general antibacterial activity of the silver ion, foam dressing without silver deposition has higher level of micro-organisms, thus represents the worst case scenario.

14.1.1 Reference of Standard: ISO-11135-1:2007

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any options selected: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any differences that may exist, if any, between the tested device and the device to be marketed: Yes. Foam dressing prior to silver deposition was used to validate the procedure. Justification: Foam dressing without silver is more difficult to sterilize (because silver itself is an antibacterial agent) thus represent the worst case scenario.

The name and address of test laboratory: In house

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Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Normative references	Yes
3	Terms and definitions	Yes
4	Quality management systems	Yes
5	Sterilizing agent characterization	Yes
6	Process and equipment characterization	Yes
7	Product definition	Yes
8	Process definition	Yes
9	Validation	Yes
10	Routine monitoring and control	Yes
11	Product release from sterilization	Yes
12	Maintaining process effectiveness	Yes

14.1.2. Validation Method

Sterilization method was validated following ISO-11135-1:2007. Ethylene oxide is used as the sterilization method. The method validation report is in Appendix 1.

Overkill approach (Half-cycle approach) is used following Annex B of the standard. A total of three consecutive experiments resulting in total inactivation of the biological indicators were performed in order to confirm the minimum exposure time. The specified exposure time doubles this minimum time. A cycle of short duration was also run to demonstrate the adequacy of the recovery technique.

Validation includes installation qualification, operational qualification, and process qualification.

Installation qualification (IQ) demonstrated that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

Operational qualification (OQ) demonstrated that the installed equipment is capable of delivering the specified process within defined tolerances.

The microbiological PQ was performed in the production chamber using defined process parameters selected to deliver less lethality than the specified sterilization process. The results demonstrated that, on application of the sterilization process, the specified requirements for sterility are met.

Physical PQ included a minimum of three planned qualification runs in which all the specified acceptance criteria are met. The results demonstrated reproducibility of the process and the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specifications.

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14.1.4. SAL Level

The SAL level was found to be NMT 10^{-6} during our experiments.

14.2 Product Packaging

Luofucon Silver Foam Dressing is packaged in single use flexible package. Packages are supplied as preformed sterile barrier systems where all the seals have been formed except at the bottom. This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. A sealant layer is applied to allow heat-sealing of the two layers together.

The material, sterile barrier system, and product packaging are designed following the suggestions provided by ISO-11607-1. They have been proven to maintain sterility of terminally sterilized medical devices during storage, transportation, and distribution, until the point of use.

Table 14.3: Summary of packaging information involved in this submission

Immediate Packaging	Enforced paper- Plastic Pouch Heat Sealed, 1pc/pouch
Intermediate Packaging	Paper Box
Outer Packaging	Corrugated Board Carton

14.3 Shelf Life Determination

The shelf life was determined by real time aging for products stored under ambient conditions. The proposed shelf life is two years.

14.3.1 Physical Properties

For real time aging test, products were stored under 25 ºC and 60% RH. Representative test results are summarized for Lot No.: S201107001; size100×100×3 mm; production date: July 12, 2011.

Both performance properties and packaging integrity were evaluated for up to two years.

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Physical properties were tested against product specifications as detailed in Section 11. All test results met specification and the results are summarized in the Table 14.4 to Table 14.6 below for three representative lots. Only average results are summarized here. For individual sample results, please see attached real time aging test report.

Table14.4: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201107001)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×3±0.3mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.112	0.108	0.113
Absorbance	≥10g/g	12.6	12.3	11.2
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.47	4.44	4.56
Loss On Drying	≤6.0%	3.1%	4.1%	4.4%

Table14.5: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201207002)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×5±0.5mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.113	0.108	0.110
Absorbance	≥10g/g	12.5	12.2	12.0
Sterility	Zero positive	Pass	Pass	Pass
pH	4.0-9.0	4.82	4.84	4.89
Loss On Drying	≤6.0%	3.1%	3.3%	3.9%

Table14.6: Representative Product Physical Properties for Two Year Real Time Aging Study (Lot S201207003)

	Specification	Zero Time	One Year	Two Year
Appearance	Porous elastomer, the surface should be clean, odorless. And there should be no damage, no strans, uniform thickness, and soft texture.	Pass	Pass	Pass
Dimension	100±5 ×100±5 ×5±0.5mm,	Pass	Pass	Pass
Density	0.09-0.18 g/cm^3	0.106	0.111	0.108
Absorbance	≥10g/g	12.6	12.4	12.1
Sterility	Zero positive	Pass	Pass	Pass

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pH	4.0-9.0	4.74	4.82	4.86
Loss On Drying	≤6.0%	3.4%	3.7%	3.9%

The silver contents of our device were tested and summarized in separate report (see attached test report No SF-HL2). Shown below in Table 14.7 to Table 14.9 are results for three lots of samples in initial, one year, and two years time points.

Table 14.7 Silver content test results, Initial time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201207002	0.700	2.80	3.02
	0.803	3.21	
	0.763	3.05	
S201207003	0.747	2.99	2.92
	0.716	2.86	
	0.728	2.91	
S201305001	0.486	3.24	3.09
	0.462	3.07	
	0.446	2.97	

Table 14.8: Silver content test results, one year time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201305001	0.401	2.67	2.81
	0.413	2.75	
	0.450	3.00	

Table14.9: Silver content test results, two year time point

LOT	Concentration (µg/mL)	Silver Content (µg/cm^3)	Average (µg/cm^3)
S201207002	0.744	2.97	2.96
	0.713	2.85	
	0.766	3.06	
S201207003	0.707	2.83	2.98
	0.751	3.00	
	0.783	3.13	

These results show that the silver contents met the product specification of 3±1 µg/cm^{3}for at least two years.

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14.3.2 Antibacterial Properties

Antibacterial properties were tested following standard AATCC-100:2004. Detailed test procedures are described in Section 18.7.2. In brief, an inoculum of the chosen challenge organism is absorbed into the test article and allowed to incubate for approximately 24 hours. The surviving challenge organisms are enumerated and compared to an untreated control.

Total of six bacteria (three Gram positive and three Gram negative) were tested:

Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 19615)
Enterococcus faecalis (ATCC 29212)
Escherichia coli (ATCC 8739)
Pseudomonas aeruginosa (ATCC 9027)
Klebsiella pneumoniae (ATCC 4352)

The antibacterial results after two years of ambient storage are presented in Table 14.5. The test was performed by Guangdong Detection Center of Microbiology, as an independent verification by third party.

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Table 14.11: Silver Foam Sample: Antibacterial activity results at Two Year Time Point. Size 100 x 100 x 3mm. The two year time point date was tested on Lot S201107001, manufacture date: July 12, 2011, test date: Sept 2013.

Bacterial	**Staphylococcus aureus ATCC 6538**			**Streptococcus pyogenes ATCC 19615**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	4.8×10^5/mL			4.7×10^5/mL		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28
Day-3 Inoculum Concentration	4.8×10^5			4.7×10^5		
Initial Contact time	1.8×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6	1.9×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.26	>4.28	>4.28	>4.28	>4.28	>4.28

Bacterial	**Enterococcus faecalis ATCC 29212**			**Escherlchia coli ATCC 8739**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.3×10^5/mL			5.2×10^5/mL		
Initial Contact time	2.1×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.0×10^6	2.0×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.32	>4.30	>4.32	>4.30	>4.30	>4.30
Day-3 Inoculum Concentration	5.3×10^5			5.2×10^5		
Initial Contact time	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.32	>4.3	>4.32	>4.30	>4.30	>4.30

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Bacterial	**Klesiella pneumonlae ATCC 4352**			**Pseudomonas aeruginosa ATCC 9027**		
Replicate	**1**	**2**	**3**	**1**	**2**	**3**
Two Year Time Point						
Day-1 Inoculum Concentration [a]	5.0×10^5/mL			5.3×10^5/mL		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
24 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
24 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
24 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32
Day-3 Inoculum Concentration	5.0×10^5			5.3×10^5		
Initial Contact time	2.0×10^6	2.0×10^6	2.0×10^6	2.1×10^6	2.0×10^6	2.1×10^6
72 Hour Contact time	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$	$<1.0 \times 10^2$
72 Hour Percent Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
72 Hour Log Reduction	>4.3	>4.3	>4.3	>4.32	>4.3	>4.32

[a]: Inoculum Concentration is presented as CFU/ 1.0ml, while 4.0 mL was actually used each time to give 1.0-2.0 x 10^6 CFU.

These results show that the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

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The summary results of antibacterial efficacy for additional two lots of aged samples are shown Table 14.12 and Table 14.13 below: For more details of the results, please see attached test report on aged samples.

Table 14.12: Summary of Antibacterial Results for Lot S201207002 over Two Years

Time point	Contact time	Average CFU (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero	0h Untreated	1.30×10^6	1.85×10^6	1.67×10^6	3.2×10^6	2.8×10^6	2.10×10^6
	0h Treated	1.25×10^6	1.88×10^6	1.57×10^6	2.7×10^6	2.8×10^6	1.89×10^6
	24h Treated	<100	<100	<100	<100	<100	<100
	72h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
1-year	0h Untreated	1.60×10^6	1.63×10^6	1.07×10^6	1.18×10^6	2.42×10^6	1.50×10^6
	0 h Treated	1.56×10^6	1.59×10^6	1.00×10^6	1.26×10^6	2.32×10^6	1.53×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
2-year	0 h Untreated	1.62×10^6	2.30×10^6	1.68×10^6	1.77×10^6	1.21×10^6	2.09×10^6
	0 h Treated	1.57×10^6	2.19×10^6	1.55×10^6	1.86×10^6	1.15×10^6	2.13×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

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Table 14.13: Summary of Antibacterial Results for Lot S201207003 over Two Years

Time point	Contact time	Average CFU (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero	0 h Untreated	1.19×10^6	1.87×10^6	1.46×10^6	2.05×10^6	1.96×10^6	1.57×10^6
	0 h Treated	1.21×10^6	1.77×10^6	1.42×10^6	2.00×10^6	1.72×10^6	1.52×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
1-year	0 h Untreated	2.07×10^6	1.41×10^6	1.45×10^6	1.83×10^6	1.18×10^6	3.4×10^6
	0 h Treated	2.01×10^6	1.34×10^6	1.36×10^6	1.74×10^6	1.12×10^6	2.8×10^6
	24 h Treated	<100	<100	<100	<100	<100	<100
	72 h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
2-year	0 h Untreated	1.00×10^6	1.71×10^6	1.33×10^6	1.65×10^6	2.15×10^6	1.07×10^6
	0h Treated	1.03×10^6	1.59×10^6	1.38×10^6	1.61×10^6	2.08×10^6	1.09×10^6
	24h Treated	<100	<100	<100	<100	<100	<100
	72h Treated	<100	<100	<100	<100	<100	<100
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

These results show that for all three representative lots over two years, the silver foam dressing is effective for all six bacteria for three days. Percent reductions are >99.99% for all bacteria after two years of storage.

14.3.3 Packaging Integrity

Packaging integrity were tested for tensile strength (following suggestions by ASTM F88), dye penetration (following suggestions by ASTM F1929-98: 2004), and sterility. The results are summarized in Table 14.14 to Table 14.16 for three representative lots. All pre-defined criteria were met for up to two years. Please see attached test reports on aged samples for more details.

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Table14.14: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201107001

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.12	2.98	2.90
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

Table14.15: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201207002

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	4.01	3.96	3.75
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

Table14.16: Representative Packaging Integrity Results for Two Year Real Time Aging Study Lot S201207003

	Specification	Zero Time	One Year	Two Year
Tensile Strength	≥1.5 N/15mm	3.99	3.94	3.73
Dye penetration	No Penetration	Pass	Pass	pass
Sterility	No Bacterial Growth	Pass	Pass	pass

14.3.3 Conclusion for Aging Tests

Based on the above results, Luofucon Silver Foam Dressing is stable for up to two year under normal storage conditions. The product shelf life is designated as two years on the labeling.

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Section 18: Performance Testing – Bench

This section contains the bench performance testing results for the Luofucon Silver Foam Dressing described in this submission. The tests including the following:

Section 18.1 Density 2
Section 18.1.1 Experimental: 2
Section 18.1.2 Results and Discussions: 2
Section 18.1.3 Justification for Application of the Data to All Four Variants: 2
Section 18.2 Absorbency Test: Free Swell Absorption Capacity 4
Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002 4
Section 18.2.2 Experimental: 5
Section 18.2.3 Results and Discussions: 5
Section 18.2.3 Justification for Application of the Data to All Four Variants: 6
Section 18.3: Loss on Drying 7
Section 18.3.1: Reference to Standard USP 34 General Chapter <731> 7
Section 18.3.2: Experimental 7
Section 18.3.3: Results and Discussions 8
Section 18.3.3 Justification for Application of the Data to All Four Variants: 8
Section 18.4: pH Value 9
Section 18.4.1: Reference to Standard USP<791> 9
Section 18.4.2: Experimental 9
Section 18.4.3: Results and Discussions: 10
Section 18.4.4 Justification for Application of the Data to All Four Variants: 10
Section 18.5: Silver Content 11
Section 18.5.1: Experimental 11
Section 18.5.3: Results and Discussions: 13
Section 18.5.4 Justification for Application of the Data to All Four Variants: 13
Section 18.6: Antibacterial Activity 15
Section 18.6.1: Reference to the AATCC 100-2004 15
Section 18.6.2: Experimental 16
Section 18.6.3: Testing Results 21
Section 18.6.4: Discussion of Testing Results 24
Section 18.7.1: Experimental 27
Section 18.7.2: Results 28
Section 18.7.3: Discussions and Conclusion 30
Section 18.8: Silver Leachablity Study 31
Section 18.8.1: Experimental 31
Section 18.8.2: Results and Discussions: 32
Section 18.9: Adhesive Strength 35
Section 18.9.1: Experimental 35
Section 18.9.2: Results and Discussions: 35

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Section 18.1 Density

Density of the immediate patient contact layer of the device is an important parameter used in product quality control.

Section 18.1.1 Experimental:

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The weight of the material was determined by calibrated balance. The width, thickness, and length of the sample were measured by calibrated ruler. Density was calculated as gram/cm^3

Acceptance Criteria: 0.09-0.18 g/cm^3

Section 18.1.2 Results and Discussions:

Shown below in Table 18.1 are exemplary density results for the three lots mentioned above.

Table18.1: Exemplary Density Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average	%RSD
S201107001	0.109	0.114	0.113	0.112	2.4%
S201207002	0.112	0.109	0.117	0.113	3.6%
S201207003	0.105	0.111	0.102	0.106	4.3%

In this exemplary measurement, average densities are 0.112, 0.113, and 0.106 g/m^3, and %RSD are 2.4, 3.6, and 4.3, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of 0.09 – 0.18 g/cm^3.

Section 18.1.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;

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- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or securing purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Density of only the skin contact layer of device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

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Section 18.2 Absorbency Test: Free Swell Absorption Capacity

Absorptive capacity of the immediate patient contact layer of the device is an important feature to assess the performance of dressings, especially these used on moderately to heavily exuding wounds.

The test was performed following BS EN 13726-1:2002: Test Methods for Primary Wound Dressings-Part 1: Aspects of absorbency. Section 3.2 of the standard: Test for Absorbency: Free Swell Absorption Capacity was chosen.

This chosen procedure is appropriate for dressings which stays physically intact and reaches maximum absorptive capacity within 30 min under the test conditions. This procedure is suitable for most types of foam dressings

Section 18.2.1: Reference to Test Standard BS EN 13726-1:2002

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: No

Any options the standard provides: Only Section 3.2: Test for Absorbency: Free Swell Absorption Capacity was chosen. The other test procedures (Sections 3.3 to 3.7) do not apply based on the nature of our product.

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: Tested In-house

Standard Section#	Section Description	Conformance
1	Scope	Yes
2	Terms and Definitions	Yes
3	Test Methods for Absorbency	Yes
3.1	Test Conditions	Yes
3.2	Free Swell Absorption Capacity	Yes
3.3	Fluid Handling Capacity	Not Apply
3.4	Fluid Affinity of Amorphous Hydrogel Dressings	Not Apply
3.5	Gelling Characteristics	Not Apply

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3.7	Dispersion Characteristics	Not Apply
3.8	Dispersion/Solubility of Hydrogel Dressings	Not Apply

Section 18.2.2 Experimental:

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The tests were carried out at at (21 ± 2) °C and relative humidity of 60 % RH ± 15 % RH.

Test solution was prepared by dissolving appropriate amount of sodium chloride and calcium chloride dihydrate in deionised water to make a solution contains 142 mmol of sodium ions and 2,5 mmol of calcium ions as the chloride salts. This solution has an ionic composition comparable to human serum or wound exudate.

A single sample was cut to 5cm x 5cm, weighed and placed in a Petri dish.

Test solution corresponding to 40 times the mass of sample was pre-warmed to (37±1) °C and added to the sample. The sample was then transferred to the oven and allowed to stand for 30 min at (37±1) °C.

The sample was suspended by forceps on one corner or by one end as appropriate, for 30 s before it was weighed.

The absorptive capacity was calculated as the average mass of solution retained per gram of sample.

Acceptance Criteria: ≥10.0g/g

Section 18.2.3 Results and Discussions:

Shown below in Table 18.2 are exemplary absorption capacity results for the three lots mentioned above.

Table18.2: Exemplary Absorption Capacity Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average (g/g)	%RSD
S201107001	11.91	12.80	13.22	12.64	5.3%
S201207002	12.51	12.19	12.68	12.46	2.0%
S201207003	12.13	12.07	13.51	12.57	6.5%

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In this exemplary measurement, average absorption capacities are 12.64, 12.46, and 12.57 g/g, and %RSD are 5.3, 2.0, and 6.5, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of free swell absorption ≥10.0g/g.

Section 18.2.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only the absorbency of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

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Section 18.3: Loss on Drying

Loss on Drying of the immediate patient contact layer of the device was tested following USP 34 General Chapter <731>: Loss on Drying

Section 18.3.1: Reference to Standard USP 34 General Chapter <731>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The Standard does not have sections	Loss on Drying	Yes

Section 18.3.2: Experimental

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The dressing was cut into 5mm x 5mm. About 1 gram was weighed. An appropriate glass-stoppered, shallow weighing bottle was dried for about 30 minutes under the same conditions to be employed in the determination and cooled to room temperature in a desiccator. The test specimen was placed in the bottle, replaced the cover, and the weight of the bottle and the contents were recorded accordingly. The loaded bottle was then placed in the drying chamber, the stopper was removed and was also left in the chamber. The drying lasted for three hours at 105 °C. Upon opening the chamber, bottle was closed promptly, and was allowed to cool to room temperature in a desiccator before weighing.

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Acceptance Criteria: ≤6%

Section 18.3.3: Results and Discussions

Shown below in Table 18.3 are exemplary loss on drying results for the three lots mentioned above.

Table18.3: Exemplary Loss on Drying Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average (%)	%RSD
S201107001	3.01%	3.14%	3.18%	3.11%	2.9%
S201207002	3.09%	3.14%	3.04%	3.09%	1.6%
S201207003	3.45%	3.60%	3.24%	3.43%	5.3%

In this exemplary measurement, average loss on drying are 3.11%, 3.09%, and 3.43%, and %RSD are 2.9, 1.6, and 5.3, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of ≤6%

Section 18.3.3 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only Loss on Drying property of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

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Section 18.4: pH Value

The dressing sample (immediate patient contact layer of the device) is leached in water and the pH value of the solution was tested following USP 34 General Chapter <791>: pH

Section 18.4.1: Reference to Standard USP<791>

All requirements in this standards were met, except for inapplicable requirements or deviations noted below

Any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed: No

Any requirements that were not applicable to the device: None

Any deviations from the standard: None

Any options the standard provides: No

Any differences that may exist, if any, between the tested device and the device to be marketed: None

The name and address of test laboratory: In House

Standard Section#	Section Description	Conformance
The monograph does not contain any sections	pH	Yes

Section 18.4.2: Experimental

The following samples were tested:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm). For this variant, only the immediate skin contact layer was tested for this property.

The layer was cut into small pieces. About one gram was weighed to the nearest 0.01g, and 25mL of distilled water without carbon dioxide was added. The solution was then stirred at (37±1)℃ for 24h to get leaching solution. The pH was calibrated and pH value of the leaching solution was determined following USP 34 General Chapter <791>

Acceptance Criteria: pH value should be between 4.0 – 9.0.

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Section 18.4.3: Results and Discussions:

Shown below in Table 18.4 are exemplary pH values for the three lots mentioned above.

Table18.4: Exemplary pH Test Results for Three Lots

Lot	Sample 1	Sample 2	Sample 3	Average	%RSD
S201107001	4.47	4.44	4.49	4.47	0.6%
S201207002	4.83	4.77	4.86	4.82	1.0%
S201207003	4.75	4.68	4.79	4.74	1.1%

In this exemplary measurement, average pH values are 4.47, 4.82, and 4.74, and %RSD are 0.6, 1.0, and 1.1, respectively, for Lots S201107001, S201207002, and S201207003. The results met the product specification of 4.0 – 9.0.

Section 18.4.4 Justification for Application of the Data to All Four Variants:

The data presented above are from three lots:

- Lot S201107001 is from the 1st variant, size 100 x 100 x 3 mm;
- Lot S201207003 is also from the 1st variant, but size 100 x 100 x 5 mm;
- Lot S201207002 is from the 3nd variant, size 150×150mm (100×100×5mm).

For Lot S201207002, the results presented above are only for the immediate skin contact layer.

For all four different variants, the immediate skin contact layer uses the same material and same manufacturing process. Some variants contain additional components such as a nonwoven layer and adhesives that are only for cosmetic or mechanical supporting purpose. These components do not contact patient skin and do not affect the effectiveness of the device.

Only pH property of skin contact layer of the device is controlled as important product quality parameter.

Therefore, the results presented above apply to the skin contacting layer of all four variants.

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PARTICLE AND FIBRE TOXICOLOGY IMPACT FACTOR 6.99

Research

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Subchronic oral toxicity of silver nanoparticles

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Abstract

Background

The antibacterial effect of silver nanoparticles has resulted in their extensive applicat on in health, electronic, consumer, medicinal, pest cide, and home products; however, silver nanoparticles remain a controversial area of research with respect to their toxic ty in biolog cal and ecological systems.

Results

This study tested the oral toxic ty of silver nanoparticles (56 nm) over a period of 13 weeks (90 days) in F344 rats following Organizat on for Econom c Cooperation and Development (OECD) test guideline 408 and Good Laboratory Pract ces (GLP). Five-week-old rats, weighing about 99 g for the males and 92 g for the females, were divided into four 4 groups (10 rats in each group): veh cle control, low-dose (30 mg/kg), middle-dose (125 mg/kg), and high-dose (500 mg/kg). After 90 days of exposure, clinical chemistry, hematology, histopathology, and silver distribution were studied. There was a signif cant decrease ($P < 0.05$) in the body weight of male rats after 4 weeks of exposure, although there were no significant changes in food or water consumption during the study period. Significant dose-dependent changes were found in alkaline phosphatase and cholesterol for the male and female rats, indicating that exposure to more than 125 mg/kg of silver nanoparticles may result in slight liver damage. Histopatholog c examination revealed a higher incidence of bile-duct hyperplasia, with or without necrosis, fibrosis, and/or pigmentation, in treated animals. There was also a dose-dependent accumulation of silver in all tissues examined. A gender-related difference in the accumulation of silver was noted in the kidneys, w th a twofold increase in female k dneys compared to male kidneys.

Conclusions

The target organ for the silver nanoparticles was found to be the liver in both the male and female rats. A NOAEL (no observable adverse effect level) of 30 mg/kg and LOAEL (lowest observable adverse effect level) of 125 mg/kg are suggested from the present study.

Background

The antibacterial activity exhibited by silver in a range of studies [1-5] has resulted in the widespread use of silver nanoparticles in bedding, washing machines, water purification, toothpaste, shampoo and rinse, nipples and nursing bottles, fabrics, deodorants, filters, k tchen utensils, toys, and humidifiers [6,7], where the main body or inner surface of the product is mixed or coated with germ-resistant nano-silver to prevent the growth of fungi and bacteria. Despite such widespread use of silver-nanoparticle-containing products, subchron c and chronic toxicity data on silver nanopart cles remain rare. The lack of exposure data on silver nanopart cles in the workplace and silver nanoparticles released from consumer products or released into the environment makes it difficult to assess the risks of using these materials. Limited data have been reported for silver nanopart cles by inhalation and oral routes of exposure. The target organs for silver nanoparticles by subchronic inhalation are the lungs and liver in male and female rats [8]. This study suggested a NOAEL (no observable adverse effect level) of 100 μg/m^3.

A LOAEL (lowest observable adverse effect level) and NOAEL have been reported for a 28-day oral toxicity study using Sprague-Dawley rats to be 300 mg/kg and 30

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mg/kg, respectively [9]. In this study, F344 rats were exposed to silver nanoparticles following the Organization for Economic Cooperation and Development (OECD) test guideline 408 (OECD, 1998), using a 13-week repeated-oral-dose toxicity protocol. The study was conducted under OECD Good Laboratory Pract ces (GLP). Clinical chemistry, histopathology, and distribut on of silver nanoparticles were investigated in blood, lungs, kidneys, brain, liver, and other organs.

Materials and methods

Silver Nanoparticles

Silver nanoparticles (CAS No. 7440-22-4) were purchased from NAMATECH, Ltd. (Daejeon, Korea), and were at least 99.98% pure. Count median diameter and geometric standard deviation of silver nanopart cles in 0.5% aqueous carboxymethylcellulose (CMC, Sigma USA) analyzed by transmission electron microscopy were 56 nm and 1.46, respectively (Figure 1).

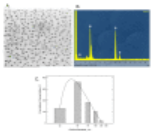


Figure 1. Transmission electron micrograph of silver nanoparticles and distribution of silver nanoparticles. The bar indicates 2 μm. A. Transmission electron micrograph of silver nanoparticles. B. Energy dispersive x-ray profile (silver nanoparticles on copper grid). C. Distribution of silver nanoparticles.

Transmission Electron Microscopy

The filters on which the silver nanoparticles in the 0.5% CMC were filtered were coated with carbon, mounted on an electron m croscope grid (200 mesh, Veco, Eerbeek, Holland), and visualized under a transmission electron microscope (TEM, Hitachi 7100). The diameters of 400 randomly selected part cles were measured at 50,000 × magnification, and the silver particles were analyzed using an energy-dispersive x-ray analyzer (EDX-200, Horiba, Japan) at an accelerating voltage of 75 kV.

Animals and Conditions

Four-week-old male and female, specific-pathogen free (SPF) Fisher 344 rats were purchased from Japan SLC Inc. (Japan) and acclimated for 7 days before starting the experiments. During the acclimation and experimental periods, the rats were housed in polycarbonate cages (maximum of 3 rats per cage) in a room with controlled temperature (22.2 ± 1.7°C) and humidity (48.4 ± 6.0%), and a 12-h light/dark cycle. The rats were fed a rodent diet (Harlan Teklad, USA) and filtered water *ad libitum*. The rats were div ded into 4 groups (10 rats in each group): vehicle control (0.5% carboxymethylcellulose, CMC), low-dose group (30 mg/kg/day), middle-dose group (125 mg/kg/day), and high-dose group (500 mg/kg/day). When the rats reached five weeks of age, they were exposed to silver nanopart cles following OECD test guideline 408 [10] by gavage for 13 weeks of repeated oral administration (dosing volumes were 10 ml/kg). Dose levels were selected based on previous observations in a 28-day oral toxicity study by Kim et al. [9]. The study was conducted under OECD Good Laboratory Pract ces.

Clinical Chemistry and Hematology

At the conclus on of the 13-wk experiment, the rats were 18 wks old. Before necropsy, food was withheld for 24 h and the rats were anesthetized w th CO_2 gas. Blood was then drawn from the abdominal aorta, collected in heparinized vacutainers, and analyzed for ALB (albumin), ALP (alkaline phosphatase), Ca (calcium), CHO (cholesterol), CRE (creatinine), gamma-GT (gamma-glutamyl transpeptidase), GLU (glucose), GOT (glutamic oxaloacetic transaminase), GPT (glutamic pyruv c transminase), IP (inorganic phosphorus), LDH (lactate dehydrogenase), MG (magnesium), TP (total protein), UA (uric ac d), BUN (blood urea nitrogen), TBIL (total bilirubin), CK (creatine phosphokinase), Na (sodium), K (potassium), Cl (chloride), TG (triglyceride), and A/G (ratio of albumin to globulin) using a b ochemical blood analyzer (Hitachi 7180, Hitachi, Japan). The blood was also analyzed for the WBC (white blood cell count), RBC (red blood cell count), Hb (hemoglobin concentration), HTC (hematocrits), MCV (mean corpuscular volume), MCH (mean corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), RDW (red cell distribut on width), PLT (platelet count), MPV (mean platelet volume), NE# (number of neutrophils), NE% (percent of neutrophils), LY# (number of lymphocytes), LY% percent of lymphocytes), MO# (number of monocytes), MO% (percent of monocytes), EO# (number of eosinophils), EO% (percent of eosinophils), BA# (number of basophils), and BA% (percent of basophils) using a blood cell counter (Hemavet 0950, CDC Tech., USA).

Organ Weights and Histopathology

After collecting blood samples, the rats were killed by cerv cal dislocation. Adrenal glands, bladder, testes, ovaries, uterus, epididymis, seminal vesicle, heart, thymus, thyroid gland, trachea, esophagus, tongue, prostate, lungs, nasal cavity, kidneys, spleen, liver, pancreas, and brain were removed carefully, weighed, and fixed in a 10% formalin solution containing neutral phosphate-buffered saline. Thereafter, the organs were embedded in paraffin, stained with hematoxylin and eosin, and examined under light microscopy.

Determination of Tissue Silver

Tissues were digested with conc. nitric ac d by using a microwave digest on system (MARS 230/60, CEM). The concentration of silver in digested fluid was analyzed with a flameless method using an atomic absorption spectrophotometer equipped with a Zeeman graphite furnace (Perkin Elmer 5100ZL, Zeeman Furnace Module, USA) based on the NIOSH 7300 method [11]. The concentration of silver in the tissue was expressed as μg/g wet weight.

Statistical Analysis

Statistical analysis was performed with SPSS (Version 12). Statistical evaluation was performed by analysis of two-tailed Student's t-test or analysis of variance (ANOVA) following multiple comparison tests with Duncan's method. The level of statistical significance was set at $p < 0.05$

Results

Animal Observation, Food Consumption, and Effect on Body and Organ Weights

There were no significant differences in food consumption and water intake between treated male and female rats and the control group (data not shown). There were no significant dose-related changes in the body weight of female rats; however, there were significant ($P < 0.05$) dose-related decreases in the body weight of high-dose male rats at 4, 5, and 7 weeks of exposure at the conclusion of the study 13 weeks, and middle-dose male rats at 10 weeks of exposure (Figure 2). No significant organ-weight changes were observed in e ther the male or female rats after 90 days except for an increase ($P < 0.05$) in the weight of the left testis for the high-dose male rats, and for decreases ($P < 0.05$) in the weight of right k dney for the low-and middle-dose female rats (Tables 1 and 2).

Table 1. Relative organ weights for male rats after 90-day oral administration of silver nanoparticles (mean ± S.D., n≥9)

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Table 2. Relative organ weights for female rats after 90-day oral administration of silver nanoparticles (mean ± S.D., n≥9)

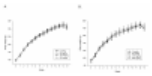


Figure 2. Body weight changes during 90-day oral administration of silver nanoparticles. A. Male. a Significant difference vs. control, p < 0.05. (10 weeks). b Significant difference vs. control, p < 0.05. (4, 5, 7~13 weeks). B. Female.

Effects on Clinical Chemistry and Hematology

There appeared to be increase ALP for male rats in the middle and high-dose groups statistically not significant (Table 3). However, there was a significant increase (P < 0.01) in alkaline phosphatase (ALP) for female rats in the high-dose groups (Table 4). A significant increase (P < 0.01) in cholesterol was also found in the middle and high-dose male rats and the high-dose female rats (Table 3 and 4). A significant increase (P < 0.05) in total bilirubin was noted in the m ddle-dose male rats (Table 3). A signif cant decrease in magnesium, protein, and inorganic phosphorus was found in the middle and high-dose female rats (Table 4). No significant changes in the hematological parameters were noted except for a significant increase (P < 0.05) in monocytes in the high-dose female rats (Table 5 and 6). The reticulocyte count for the low-dose female rats decreased signif cantly (p < 0.05) when compared with the control group (Table 7). Coagulation time in terms of the active partial thromboplastin time (APTT) and prothrombin time (PT) did not show any significant changes when compared with the control group (Figure 3).

Table 3. Serum values for male rats after 90-day oral administration of silver nanopart cles (mean ± S.D.)

Table 4. Serum values for female rats after 90-day oral administration of silver nanopart cles (mean ± S.D.)

Table 5. Hematological values for male rats after 90-day oral administration of silver nanoparticles (mean ± SD)

Table 6. Hematological values for female rats after 90-day oral administrat on of silver nanoparticles (mean ± SD).

Table 7. Reticulocyte counts for male and female rats after 90-day oral administration of silver nanoparticles (n = 5, EA/1000, mean ± SD)

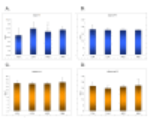


Figure 3. Coagulation times for male and female rats: A, male prothrombin time (PT); B, male active partial thromboplastine time (APPT); C, female PT; D, female APPT. (Error bars indicate standard deviation.)

Histopathologic Examination

In the liver, minimal bile-duct hyperplasia was identified in 4/10, 7/10, 8/10, and 6/10 of control, low, middle, and high-dose male rats, respectively (Table 8, Figure 4C). The higher incidence of bile-duct hyperplasia in treated male rats suggests a minimal effect due to silver nanoparticles in the treated groups. Minimal bile-duct hyperplasia was also present in 3/10, 7/10, 8/10, and 7/10 of the control, low, middle, and high-dose female rats, respectively (Table 9). Focal, multifocal, or lobular necrosis was noted in 0/10, 4/10, 5/10, and 4/10 of the control, low, middle, and high-dose male rats, respectively, and 0/10, 2/10, 2/10, and 2/10 of the control, low, middle, and high-dose female rats, respectively (Table 8 and 9, Figure 4B and 4D). The higher incidence of bile-duct hyperplasia, with or without necrosis, fibrosis, and/or pigmentat on, in the treated animals also suggests a treatment-related effect. Although there appeared to be a slight increase of minimal tubular basophilia in the kidneys of high-dose male rats, these changes were not statistically significant and thus not considered to be test article exposure related. Tubular basophilia were also more prevalent in the male rats compared to the female rats (Table 8). Minimum or mild renal unilateral or bilateral mineralization was observed in 5/10, 8/10, 7/10, and 9/10 of the control, low, middle, and high-dose female rats, respectively, indicating a treatment-related effect.

Table 8. Histopathological findings for male rats after 90-day oral administration of silver nanoparticles

Table 9. Histopathological findings for female rats after 90-day oral administration of silver nanoparticles

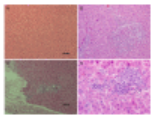


Figure 4. Histopathological findings in liver: (A) control liver, (B) multiple foci of inflammatory cell infiltrates, including eosinophils, especially around central vein and portal areas (C) bile duct hyperplasia, and (D) several foci of inflammatory cell infiltration, especially around central vein and sinusoid on hepatic lobules. Bar ind cates 100 μm. A. Control (×100). B. High dose (×100). C. High dose (×100). D. High dose (×200).

Histopathologic examination of lung tissue did not show any treatment-related effects.

In the intestines, pigmentation of villi was observed in 0/10, 0/10, 8/10, and 8/10 of the control, low, middle, and high-dose male rats, respectively (Table 8). This dose-dependent increase in the pigmentation of the villi indicated an apparent treatment-related effect (Figure 5). In contrast, there was a slight treatment-related increase in pigmentation of intestinal villi in female rats (Table 9).

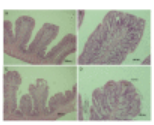


Figure 5. Histopathological findings in intestines of male rats dosed with 500 mg/kg silver nanoparticles for 90 days. A. Control male (×40). B. Control male (×100). C. High-dose male (×40). D. High-dose male (×100).

Silver Distribution in Tissues

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There was a statist cally significant ($P < 0.01$) dose-dependent increase in the silver concentration of all the tissue samples from the groups exposed to silver nanopart cles in this study (Table 10). In addition, a two-fold higher accumulation of silver in the kidneys of female rats when compared with the male rats occurred across all the dose groups indicating a marked gender-dependent distribution.

Table 10. Tissue silver content after 90-day oral administration of silver nanoparticles

Discussion

Silver nanoparticles are widely used as bacteric dal agents in consumer products, but their potential effects in humans remain poorly understood. Silver at doses below levels that cause argyria or argyriosis are generally considered to be relatively non-toxic [12]. Wijnhoven et al. have hypothesized that the toxic effects of silver are proportional to free silver ions, but it is unclear how this relates to silver nanoparticles. Absorption of silver after oral administration has been shown to be subject to a first-pass effect through the liver, resulting in excretion into the bile [13]. Uncleared silver has been shown to be deposited in the renal glomerular basement membrane [14-17], mesangium [18], Kupffer cells, and sinusoid endothelium cells in the liver [15].

Unlike the 28-day study of Kim et al. [9], the present study shows intestinal pigmentation and effects from exposure to silver nanoparticles. Dose-dependent increases in the silver concentrations in the intestinal villi, as observed in this and other reports [19], and in the blood, indicate that the orally absorbed silver from nanopart cles is able to enter the blood circulation and be distributed to other organs. Since similar effects have not been prev ously reported for soluble silver, there is a possibility that these effects are due to particles as opposed to ionized silver.

Increases in renal silver reported in the current study are consistent with literature showing that ionized silver is deposited in the renal glomerular basement membrane [14-17] and mesangium [18]. The gender-related distribution of silver nanoparticles in the kidneys was also consistent with the results from the 28-day [9], 90-day oral, and 90-day inhalat on studies [8]. The average nanoparticle sizes used in the 28-day and 90-day inhalation experiments were 15 nm and 18-19 nm, respectively, while the average nanopart cle size used in the 28-day and 90-day oral tox city studies was 60 nm and 56 nm, respectively. Common treatment-related endpoints and distribution were found in all these studies ind cating that distribution and toxicity do not appear to be dependent on particle size in the tested range or route of administration.

In previous reports, the target organs for silver nanoparticles were shown to be the liver in a 28-day oral toxicity study [9] and the liver and lungs in a 90-day inhalation study [8]. The results of the current study are consistent with previous reports with respect to the liver as the target organ and the tissue distribution of silver originating from nanoparticles. Liver toxicity as evaluated by histopathology included bile-duct hyperplasia and increased foci, which was consistent with the pathologic observations in the 28-day [9] oral toxicity and 90-day inhalation [8] toxicity studies. Increases in alkaline phosphatase and cholesterol were also consistent with the liver toxicity reported by Kim et al. and Sung et al.

In contrast to the 90-day inhalation study, no coagulation effects on peripheral blood were observed. Since there is similar hepatic pathology in the two studies, it is not clear whether increased coagulation times were due to hepatic injury in the inhalation study or some other mechanism.

Inhaled silver nanoparticles have been shown to cause lung inflammation [8]. These effects may be due to particle size since gold nanoparticles (which are not likely to be ionized) show similar effects [20]. Our very limited data makes it tempting to hypothesize that effects from silver nanoparticles are not only due to ionization of silver from the surface of silver nanoparticles, but may originate (at least in part) from direct effects of nanoparticles. The relationship between particle effect and effect from ionized silver could be tested by quantitatively examining target tissues for the presence of nanoparticles with a concurrent measurement of tissue ionized silver as opposed to measuring total tissue silver alone. If silver nanoparticles have part cle-related effects which are tissue specific and signif cant compared to effects from ionized silver, t will be important to incorporate such differences into future occupat onal and environmental risk assessments.

Conclusions

A LOAEL (lowest observable adverse effect level) of 125 mg/kg and a NOAEL (no observable adverse effect level) of 30 mg/kg are suggested from the current 90-day oral toxicity study. The LOAEL from this study is significantly lower than the LOAEL of 300 mg/kg derived from the 28-day oral toxicity study (Kim et al., 2008). However, the NOAEL derived from this study is consistent with the NOAEL of 30 mg/kg derived from the 28-day oral study (Kim et al., 2008).

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

IJY headed the study and performed pathologic analyses together with MYS, YHC, HKC, IHK and drafted the manuscript with YSK and BK. YSK headed all animal treatments with MYS, KSS, and HRR. JDP and JHL contributed to the distribution study. IJY, BK and KHO conceived and designed the study. All authors reviewed and interpreted data and read and approved the final manuscript.

Acknowledgements

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From: Murphey, Sheila A <Sheila.Murphey@fda.hhs.gov>
To: 'Cyshen@aol.com' <Cyshen@aol.com>
Cc: Arepalli, Sambasiva <Sambasiva.Arepalli@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: Question on Antibacteria Test (AATCC-100)
Date: Tue, May 29, 2012 9:43 am

Dear Chengyu Shen,

Thank you for your email. I must point out that I have not been consulted on your file and that I know nothing about its comments or about the comments from your initial review. I do not expect that situation to change. The only advice which I can provide to you is on the general principles of antimicrobial performance testing.

First, please note that FDA does not recognize any "standard test methods" for the performance of in vitro antimicrobial performance testing. The very wide variety of devices, proposed intended uses and antimicrobial agents seen by the agency very frequently requires that "standard" test methods be modified in order to best reflect the simulated conditions of use of the device being evaluated. The Agency does not object to modifications of test methods as long as they are scientifically sound and fully described.

The following principles should be observed in the design of your planned performance assays:
1. The test conditions should simulate, as closely as possible, the conditions of use of your device. For a wound dressing, this does mean avoiding excess fluid in the test environment
2. The device challenge inoculum should be measured at the time of device challenge.
3. An effective neutralizing agent must be used for enumeration of your assay results. This neutralizing agent should be clearly identified and you should submit the neutralization validation data with the rest of your test results.
4. Your assay should include challenge of the base device without the added antimicrobial agent as a control for non-specific material antimicrobial effects in your device
5. You should use a significant challenge inoculum for your assay; the Agency advises a concentration of at least 6 log10 CFU/mL. The volume in which you deliver this challenge can vary; however, you should measure your challenge inoculum in each assay that you perform.
6. You should identify and report the Limit of Quantitation (LOQ) of your assay - the limit below which your counts are no longer accurate; this is frequently 2 log10 CFU/mL and is why you need a significant inoculum in order to reliably detect a significant reduction in that inoculum
7. I do not advise any sponsor to seek performance claims by re-inoculating a specimen previously challenged with a microbial inoculum. This is particularly true beyond 72 hours, when microbial death due to nutrient deprivation can begin to occur.

If you wish to seek a claim for prolonged activity, the most straightforward way to test this is to use dressing specimens, including the needed controls, which have been maintained under simulated use (leach off) conditions for the number of days for which you seek a claim. After 6 or 7 days (whichever you prefer for your labeling claims) of simulated use exposure, transfer the specimens aseptically to a new sterile dish and perform the microbial challenge test as you would for unused product.

Be sure that whatever test methods you use in performance testing, they are clearly described in complete detail in your submission.

I hope that this information will be of use.

Regards,

Sheila A. Murphey, MD

Sheila A. Murphey, MD
Medical Officer, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health, FDA
10903 New Hampshire Ave., Bldg 66, Room 2510, Silver Spring, MD 20993-0002

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Phone 301-796-6302 Fax 301-847-8109
sheila.murphey@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Cyshen@aol.com [mailto:Cyshen@aol.com]
Sent: Tuesday, May 29, 2012 8:01 AM
To: Murphey, Sheila A
Subject: Question on Antibacteria Test (AATCC-100)

Dear Dr Murphy:

This is Chengyu Shen from Huizhou Foryou Medical Co., Ltd. We got your contact information from Dr Aprepalli. We are performing antibacterial testing on Silver Aginate Dressing per standard AATCC-100 as part of our effort to address deficiency letter for our 510(k) submission K120181. However, we have the following question, can you please kindly advise us?

The AATCC-100 requires inoculation 1 mL (10e6 population) of bacteria at day-1 and day-6 (since we are making 7 day claim) each for total of 2ml. However, our dressing is having difficulty to absorb 2 ml solution. In this case, can we use 0.5ml (day-1) + 0.5 ml (day-6), but doubled bacteria population (e.g. 2x10e6)?

Please kindly advise.

Chengyu Shen
Huizhou Foryou Medical Co., Ltd

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K141619/S003

FDA CDRH DMC
MAR 24 2015
Received

Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S003, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

The revision is based on FDA recent 2nd deficiency letter on K141619

Two copies are included: One paper copy and one eCopy
The eCopy is an exact duplicate of the paper copy.

The submission is revised to address your review comments. The details of the revision are summarized below:

FDA Comment 1:

You stated that your device has "an antibacterial effective time of three days." However, after close inspection of your protocol, it is clear that contact between your device and bacteria was technically only assessed for 24 hours, regardless of time point. With regards to conditioning of the device prior to inoculation, only 100 µL simulated wound fluid (SWF) was applied to the device every 24 hours. Because the volume is smaller than what would be needed to saturate the sample, it is not clear that the conditioning protocol leached the maximum amount of silver from the dressing sample, as might occur during use. We believe your experimental design should ideally measure the device's ability to inhibit bacterial growth on the dressing under continuous exposure to bacteria over your claimed time period. We therefore do not believe that this testing is sufficient to support a claim antibacterial preservative effectiveness for 3 days. Please consider one of the following options…….

Our Response:

We take the option 1, and revised test report is included. Test protocol has been reviewed by FDA before the test started.

1-CD
45

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary of new antibacterial test results:

Time point	Contact time	Bacteria (ATCC No.)					
		6538	29212	19615	8739	9027	4352
Zero contact	Initial inoculum concentration (CFU/mL)	1.84×10^6	1.66×10^6	2.76×10^6	1.49×10^6	1.71×10^6	1.40×10^6
	Treated sample (CFU)	2.89×10^6	2.95×10^6	4.80×10^6	2.64×10^6	3.06×10^6	2.46×10^6
		2.70×10^6	2.40×10^6	4.54×10^6	2.45×10^6	3.09×10^6	2.41×10^6
		3.10×10^6	2.59×10^6	4.90×10^6	2.46×10^6	3.19×10^6	2.76×10^6
	Control sample (CFU)	3.35×10^6	2.98×10^6	5.28×10^6	2.76×10^6	2.95×10^6	2.59×10^6
		3.01×10^6	2.46×10^6	4.66×10^6	2.35×10^6	3.43×10^6	2.98×10^6
		3.09×10^6	2.86×10^6	4.89×10^6	2.55×10^6	3.09×10^6	2.50×10^6
72 hour contact	Treated sample (CFU)	<250	<250	<250	<250	<250	<250
		<250	<250	<250	<250	<250	<250
		<250	<250	<250	<250	<250	<250
	Control sample (CFU)	2.26×10^9	1.76×10^9	4.79×10^8	2.48×10^9	2.35×10^9	3.21×10^8
		1.85×10^9	3.79×10^9	3.76×10^8	0.88×10^9	2.21×10^9	4.45×10^8
		0.99×10^9	1.20×10^9	5.71×10^8	3.58×10^9	4.44×10^9	6.16×10^8
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
	Average Log reduction	4.064	4.025	4.278	4.003	4.095	4.008
	Control plate	no colony	no colony	no colony	no colony	no colony	no colony

Challenge organisms

Test Organism	Stain
Enterococcus faecalis	ATCC 29212
Escherichia coli	ATCC 8739
Klebsiella pneumoniae	ATCC 4352
Pseudomonsa aeruginosa	ATCC 9027
Staphylococcus aureus	ATCC 6538
Streptococcus pyogenes	ATCC 19615

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FDA Comment 2:

If you choose to conduct additional testing (per Deficiency 1a, 1b above):
Your test protocol appears to indicate that, following the addition of the neutralization broth, that bacteria are combined with the hot nutrient agar before it cools and solidifies. This method could lyse, inactivate, and/or hinder bacterial growth depending on temperature and distort your test results. Instead, please first prepare the nutrient agar plates and let them cool/solidify without adding bacteria. Prior to using these plates, place a control plate in the incubator for 24 hours to make sure that no contamination of other bacteria will grow. After performing your serial dilution on your samples, plate each dilution evenly on the surface of your nutrient agar plates using a plate spreader.

Our Response:

We have adapted the FDA suggested methodology in our new test.

FDA Comment 3:

In your January 10, 2015 response, you stated that you revised your labeling to address Deficiency 8e of our September 19, 2014 letter. However, your submitted labeling did not reflect those revisions. Per Deficiency 8e, please remove the sentence "The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment" from your labeling (Section 13, p. 3).

Our Response:

Corrected

FDA Comment 4:

You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

Our Response:

The packaging integrity was tested over the two year real-time aging period. These reports were in our January 10, 2015 response, with the reports names below:

014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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These reports are included again this time for your convenience.

FDA Comment 5:

Your labeling contains symbols that are not accompanied by explanatory text. Please note 21 CFR 801.15(c)(1), which states that "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language." Thus, please revise your labeling such that all symbols are accompanied by explanatory text.

Our Response:

Corrected in Section 13

List of Documents included in this supplemental submission (S003):

001_Response to K141619 2nd Deficiency
002_New Antibacterial Testing Report
003_Section 13_Labeling RE3
004_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
005_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
006_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen Charles Shen

Charles Shen, Official Correspondent
Date: March 20, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Device Evaluation
510(k) Mail Center
Center for Device and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

RE: K141619/S003, Revision for 510(k) of Luofucon Silver Foam Dressing

Dear Sir/Madam:

Please find enclosed are two copies of **Revision** for K141619, Luofucon Silver Foam Dressing, manufactured by Huizhou Foryou Medical Device Co., Ltd

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Our Response:

We take the option 1, and revised test report is included. Test protocol has been reviewed by FDA before the test started.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		6538	29212	19615	8739	9027	4352
Zero contact	Initial inoculum concentration (CFU/mL)	1.84×10^6	1.66×10^6	2.76×10^6	1.49×10^6	1.71×10^6	1.40×10^6
	Treated sample (CFU)	2.89×10^6 2.70×10^6 3.10×10^6	2.95×10^6 2.40×10^6 2.59×10^6	4.80×10^6 4.54×10^6 4.90×10^6	2.64×10^6 2.45×10^6 2.46×10^6	3.06×10^6 3.09×10^6 3.19×10^6	2.46×10^6 2.41×10^6 2.76×10^6
	Control sample (CFU)	3.35×10^6 3.01×10^6 3.09×10^6	2.98×10^6 2.46×10^6 2.86×10^6	5.28×10^6 4.66×10^6 4.89×10^6	2.76×10^6 2.35×10^6 2.55×10^6	2.95×10^6 3.43×10^6 3.09×10^6	2.59×10^6 2.98×10^6 2.50×10^6
72 hour contact	Treated sample (CFU)	<250 <250 <250	<250 <250 <250	<250 <250 <250	<250 <250 <250	<250 <250 <250	<250 <250 <250
	Control sample (CFU)	2.26×10^9 1.85×10^9 0.99×10^9	1.76×10^9 3.79×10^9 1.20×10^9	4.79×10^8 3.76×10^8 5.71×10^8	2.48×10^9 0.88×10^9 3.58×10^9	2.35×10^9 2.21×10^9 4.44×10^9	3.21×10^8 4.45×10^8 6.16×10^8
	% Reduction	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
	Average Log reduction	4.064	4.025	4.278	4.003	4.095	4.008
	Control plate	no colony	no colony	no colony	no colony	no colony	no colony

Challenge organisms

Test Organism	Stain
Enterococcus faecalis	ATCC 29212
Escherichia coli	ATCC 8739
Klebsiella pneumoniae	ATCC 4352
Pseudomonsa aeruginosa	ATCC 9027
Staphylococcus aureus	ATCC 6538
Streptococcus pyogenes	ATCC 19615

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

FDA Comment 2:

If you choose to conduct additional testing (per Deficiency 1a, 1b above):
Your test protocol appears to indicate that, following the addition of the neutralization broth, that bacteria are combined with the hot nutrient agar before it cools and solidifies. This method could lyse, inactivate, and/or hinder bacterial growth depending on temperature and distort your test results. Instead, please first prepare the nutrient agar plates and let them cool/solidify without adding bacteria. Prior to using these plates, place a control plate in the incubator for 24 hours to make sure that no contamination of other bacteria will grow. After performing your serial dilution on your samples, plate each dilution evenly on the surface of your nutrient agar plates using a plate spreader.

Our Response:

We have adapted the FDA suggested methodology in our new test.

FDA Comment 3:

In your January 10, 2015 response, you stated that you revised your labeling to address Deficiency 8e of our September 19, 2014 letter. However, your submitted labeling did not reflect those revisions. Per Deficiency 8e, please remove the sentence "The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment" from your labeling (Section 13, p. 3).

Our Response:

Corrected

FDA Comment 4:

You stated that packaging integrity was tested over the two year real-time aging period. However, test reports were not provided (September 19, 2014, Deficiency 6b). You stated in your January 10, 2015 response that you provided package integrity testing reports. However, we could not locate these reports. Please provide these reports for our review or indicate where these reports were in your January 10, 2015 response.

Our Response:

The packaging integrity was tested over the two year real-time aging period. These reports were in our January 10, 2015 response, with the reports names below:

014_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
015_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
016_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

These reports are included again this time for your convenience.

FDA Comment 5:

Your labeling contains symbols that are not accompanied by explanatory text. Please note 21 CFR 801.15(c)(1), which states that "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language." Thus, please revise your labeling such that all symbols are accompanied by explanatory text.

Our Response:

Corrected in Section 13

List of Documents included in this supplemental submission (S003):

001_Response to K141619 2nd Deficiency
002_New Antibacterial Testing Report
003_Section 13_Labeling RE3
004_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201107001
005_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207002
006_Real_Time_Aging_Report_of_LUOFUCON_Silver_Foam_Dressing S201207003

We believe the revised submission has addressed all your comments. If you have any questions regarding this revised submission, please contact me at 001-608-217-9358. My facsimile number is 425-930-2155, and my email address is: cyshen@aol.com

Kind regards,

Sincerely,

Charles Shen

Charles Shen, Official Correspondent
Date: March 20, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 13: Proposed Labeling

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

The following labels are included:

13.1 User Manual 3
13.2 Pouch Label 5
13.3 Box Label 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use

Rx Only
Version: A/0

Description
LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure containing silver particles which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. The total maximum amount of silver partilces is 4ug/cm^3. The silver is present as a preservative to inhibit bacterial colonization within the dressing. LUOFUCON® Silver Foam Dressing has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.
The **Silver Foam Dressing with PU Backing** consists of silver foam and breathable polyurethane film for waterproof. The **Bordered Silver Foam Dressing** is silver foam on a PU/PET film or non-woven coated with acrylic adhesive and extends to act as a border adhesive to allow fixation without secondary dressing or fixation bandage.

Indications
LUOFUCON® Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:
1. Ulcers(venous,arterial,diabetic)
2. Pressure sores
3. Donor sites
4. Surgical incisions
5. Surgical excusions
6. Burns(1st and 2nd degree)

Silver serves as a preservative against bacterial growth in the dressing material

Contraindications
Do not use LUOFUCON® Silver Foam Dressing on patients who is silver allergy.

In Vitro Study Results:
This device has been shown to have 4 log bacterial reduction up to 3 days in vitro against the following bacteria:

Proven Antibacterial Effectiveness	
Bacterial	72 Hour Log Reduction
Staphylococcus aureus (ATCC 6538)	4 Log
Streptococcus pyogenes (ATCC 19615)	4 Log
Enterococcus faecalis (ATCC 29212)	4 Log
Escherlchia coli (ATCC 8739)	4 Log
Klesiella pneumonlae (ATCC 4352)	4 Log
Pseudomonas aeruginosa (ATCC 9027)	4 Log

Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to the wound area.
3. Cover and secure the LUOFUCON® Silver Foam Dressing with a secondary dressing.
4. The dressing should be left on the skin for no more than three days.

Warnings

1. This product is single use. Do not use it if the pouch is damaged or opened.
2. Do not suggest to use this product on dry wound.
3. Do not use LUOFUCON® Silver Foam Dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Specifications (Including 3mm and 5mm)

Foam or With PU Backing	PU or Non-woven Adhesive
50×50	50×50(20×20)
75×75	100×60(60×30)
100×100	100×100(50×50)
125×100	150×150(100×100)
150×150	180×180(110×110)
200×100	
200×150	Unit: mm

Storage and disposal

1. Please store the product in cool and dry place, and avoid light.
2. Disposal should be handled according to local environmental procedures.

Shelf life: 2 years from date of manufacture
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, P.R.China
Tel: +86-752-5302188 **Fax**: +86-752-5302088
Website: www.foryoumedical.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.2 Pouch Label

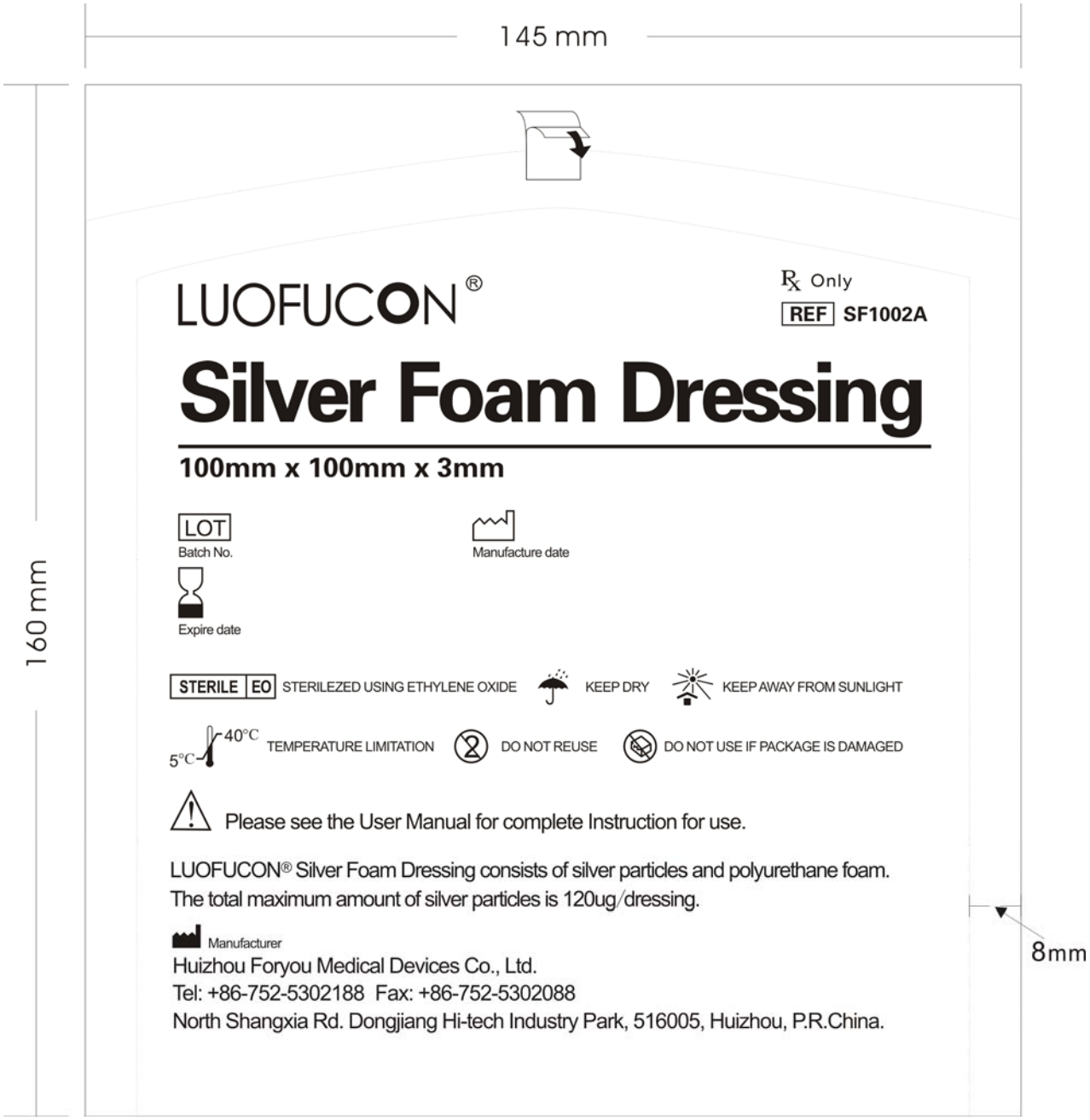
Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Section 13: Labeling: Prescription

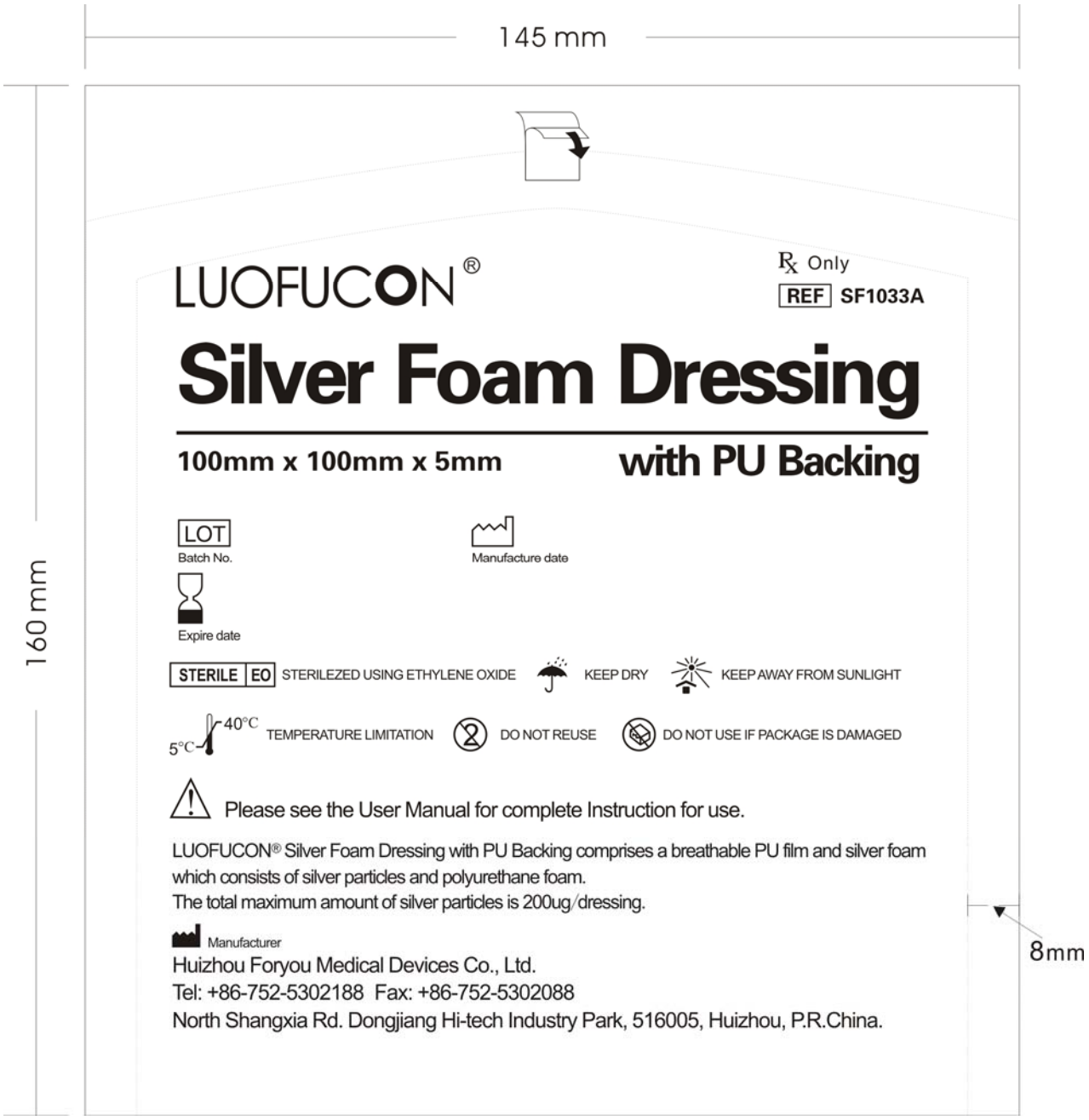
Variant 1:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

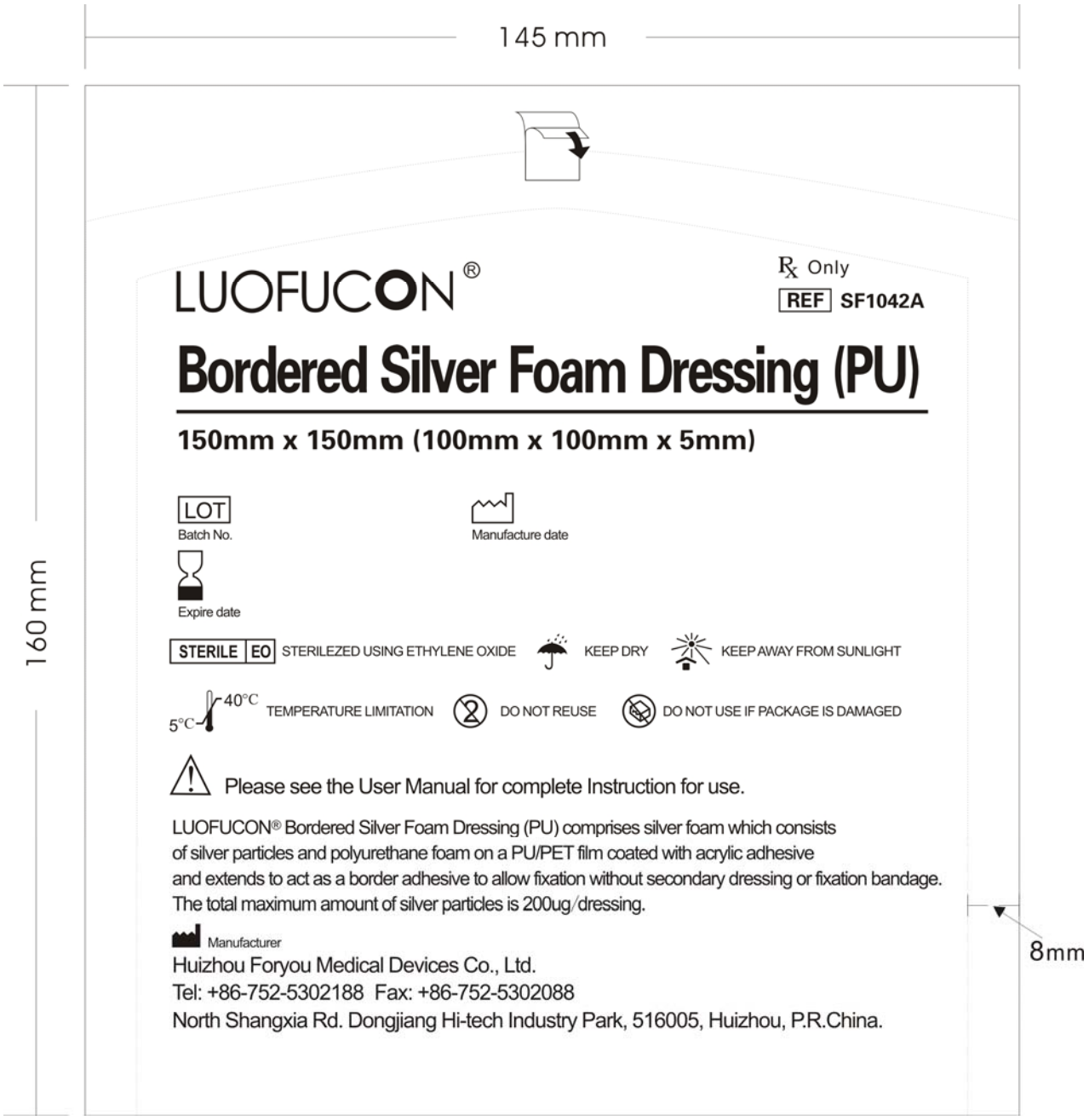
Variant 2:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

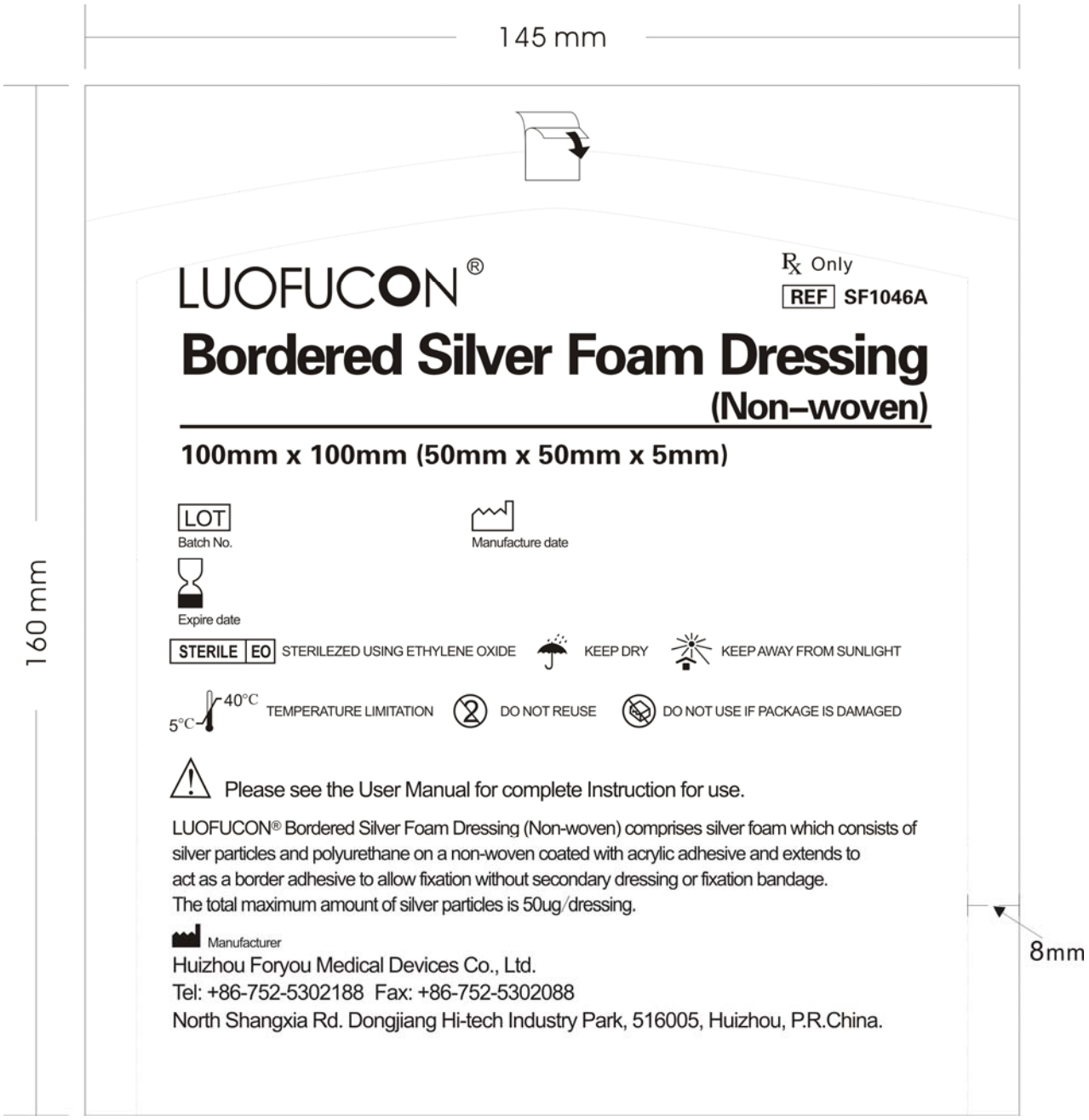
Variant 3:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Variant 4:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

13.3 Box Label

Note: The letters may seem small in the inserted picture blow, but are much larger in actual label, as actual labels are bigger than an A4 paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

Variant 1



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Variant 2:



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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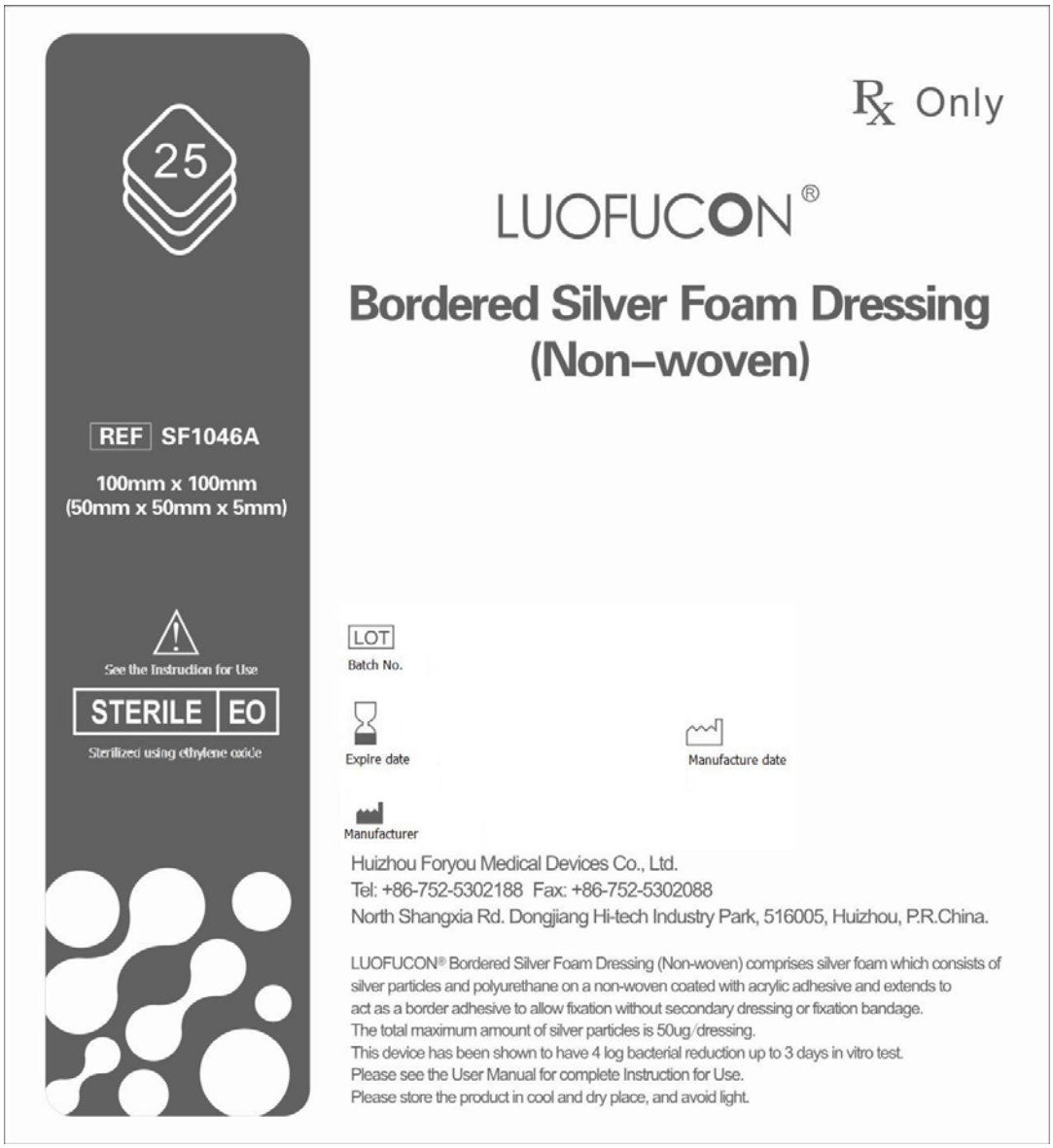
Variant 3:



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Variant 4:



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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

CON1415476- K141619/S001
Microbiology Consult Review on the **Luofucon Silver Foam Dressing**

Date: September 18, 2014
To: Peter Yang Lead Reviewer
From: Karoll J. Cortez, MD. MHS Reviewer Infection Control Devices Branch, DAGRID/ODE
Through: Elizabeth Claverie, Branch Chief, Infection Control Devices Branch, DAGRID/ODE

Recommendation: Additional information required

BACKGROUND

The sponsor firm **Huizhou Foryou Medical Devices CO, Ltd.** has submitted a 510(k) for their product: **Luofucon Silver Foam Dressing.** A microbiology assessment was requested to INCB. In this review I have focused on Section 18: "Performance testing bench". However, I also reviewed the following sections in the submission as pertain to the antimicrobial claim only:

- Indications for Use
- Sterilization
- 510(k) Summary
- Device Description

Other information related to the device:
Common name: Silver foam Dressing
Classification name: Dressing, wound, Drug
Product Code: FRO
Regulation number: Unclassified
Review Panel: General and Plastic Surgery

INDICATION FOR USE

The Luofucon is indicated for exude absorption and the management of partial
To full thickness wound. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

- Surgical incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

The product is for prescription used only (part 21 CFR 801 Subpart D)

PREDICATE DEVICE INFORMATION

K110062: "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." Norcross, GA

DEVICE DESCRIPTION

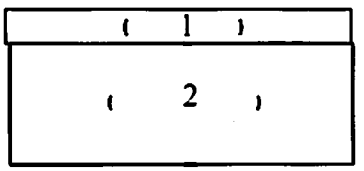
The sponsor provided the following information:

Luofucon is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal. The polyurethane material consists of metallic silver that provides effective protection of the dressing against bacterial contamination. The silver protects the dressing from a broad spectrum of bacteria over three days, based on in vitro laboratory testing. Odor reduction results from the antibacterial effect in the dressing.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes (See Table 11.1).

A second variant, non-adhesive backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non-porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes (See Table 11.2, Table 11.5).



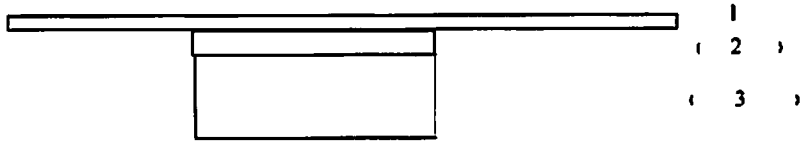
Illustrative drawing of the second variant: (1)) Thin polyurethane backing layer for cosmetic purpose (2) Thick polyurethane wound contacting layer

A third adhesive variant, PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of

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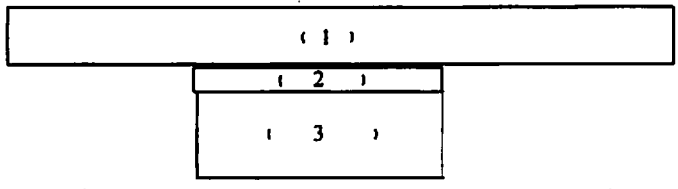
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second layer is a large thin film of Poly (ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.3, Table 11.5).



Illustrative drawing of the third variant: (1) Thin PET layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

A fourth adhesive variant, non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non-woven material is made from viscose rayon fiber and poly (ethylene terephthalate) fiber. The backing polyurethane layer and non-woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes (See Table 11.4, Table 11.5).



Illustrative drawing of the fourth variant: (1) Non-woven layer (2) Thin polyurethane backing layer (3) Thick polyurethane wound contacting layer

For the third and fourth variants, the adhesive is composed of 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

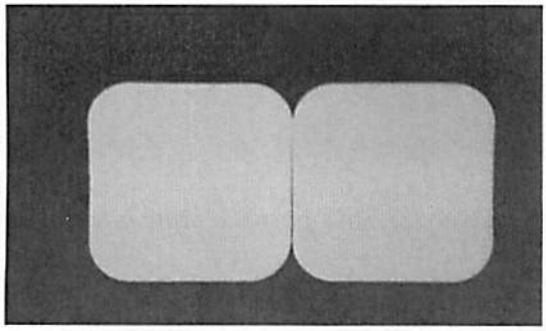
The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Pictures, drawings, and size specifications of the dressings involved in this submission are summarized in the Table 11.1 to Table 11.4 below. Secondary layer information is summarized in Table 11.5.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.1: Pictures, Drawings, and Size Specifications of the Non-Backing Variant of the Silver Foam Dressing

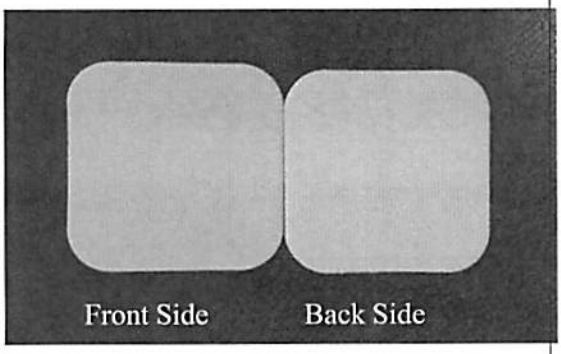
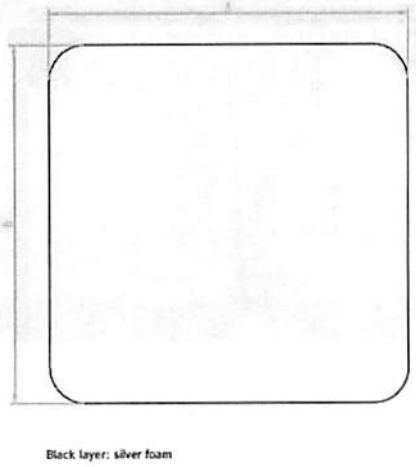
Representative Picture	Drawing
 Front Back	

Size			
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.2: Pictures, Drawings, and Size Specifications of the Non-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing
	

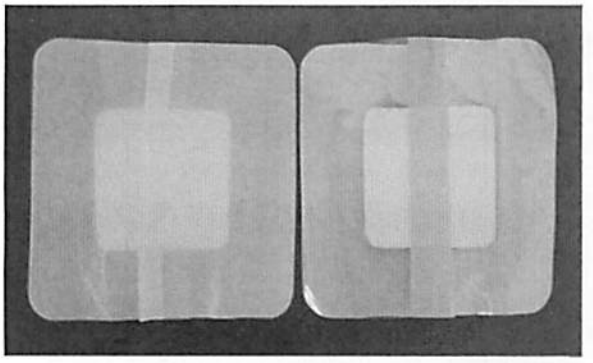
Size

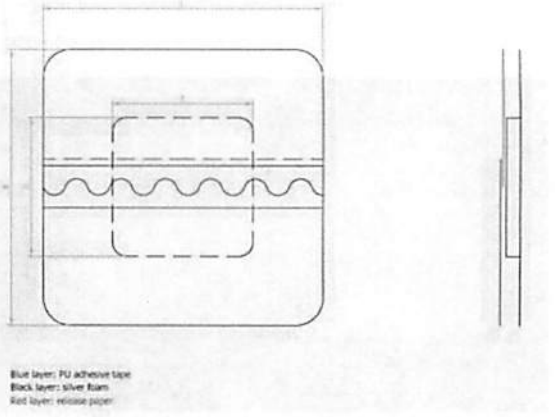
Spec. (mm)	Length, mm	Width, mm	Thickness, mm
50×50×3	50	50	3
75×75×3	75	75	3
100×100×3	100	100	3
120×100×3	120	100	3
120×120×3	120	120	3
150×100×3	150	100	3
150×150×3	150	150	3
200×100×3	200	100	3
200×150×3	200	150	3
50×50×5	50	50	5
75×75×5	75	75	5
100×100×5	100	100	5
120×100×5	120	100	5
120×120×5	120	120	5
150×100×5	150	100	5
150×150×5	150	150	5
200×100×5	200	100	5
200×150×5	200	150	5

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.3: Pictures, Drawings, and Size Specifications of the PU -Adhesive Backing Variant of the Silver Foam Dressing





Back Side Front Side

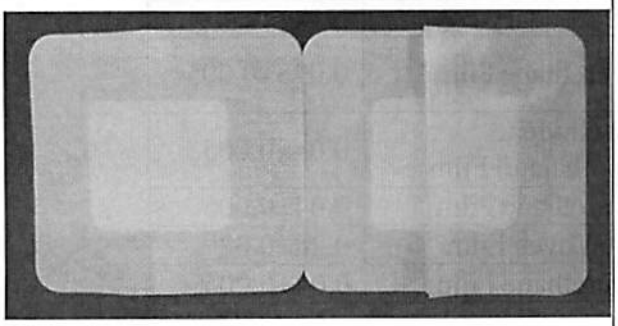
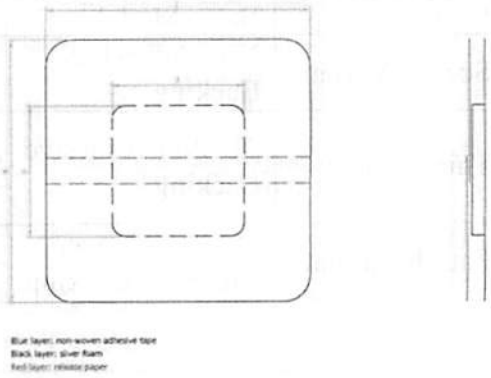
Size					
Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length/L, mm	PU Adhesive Tape width/W, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.4: Pictures, Drawings, and Size Specifications of the Non-Woven-Adhesive Backing Variant of the Silver Foam Dressing

Representative Picture	Drawing [a]
 Front Side Back Side	

Size

Spec. (mm) Adhesive backing area (Pad Size)	PU Adhesive Tape length, mm	PU Adhesive Tape width, mm	Silver Foam length, mm	Silver Foam width, mm	Silver Foam thickness, mm
50×50 (20×20×3)	50	50	20	20	3
100×60 (60×30×3)	100	60	60	30	3
100×100 (50×50×3)	100	100	50	50	3
150×150 (100×100×3)	150	150	100	100	3
180×180 (110×110×3)	180	180	110	110	3
50×50 (20×20×5)	50	50	20	20	5
100×60 (60×30×5)	100	60	60	30	5
100×100 (50×50×5)	100	100	50	50	5
150×150 (100×100×5)	150	150	100	100	5
180×180 (110×110×5)	180	180	110	110	5

[a]: Blue line: adhesive tape; black line: foam dressing; red line: release paper.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11.5: Secondary Layer Information Summary

Variant	Variant	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non-Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Broad spectrum antimicrobial effect against Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3+/-1 $\mu g/cm^3$ silver particles

MICROBIOLOGY CONSULTATION

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	na	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EO = 0.01 mg/day ECH = 2 mg/day	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.))	Conforms to 11135-2007 Standard.	
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	No	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Not provided	
5. A description of the packaging (not including package integrity test data):	Immediate Packaging Enforced paper- Plastic Pouch Heat Sealed, 1pc/pouch Intermediate Packaging Paper Box Outer Packaging Corrugated Board Carton	

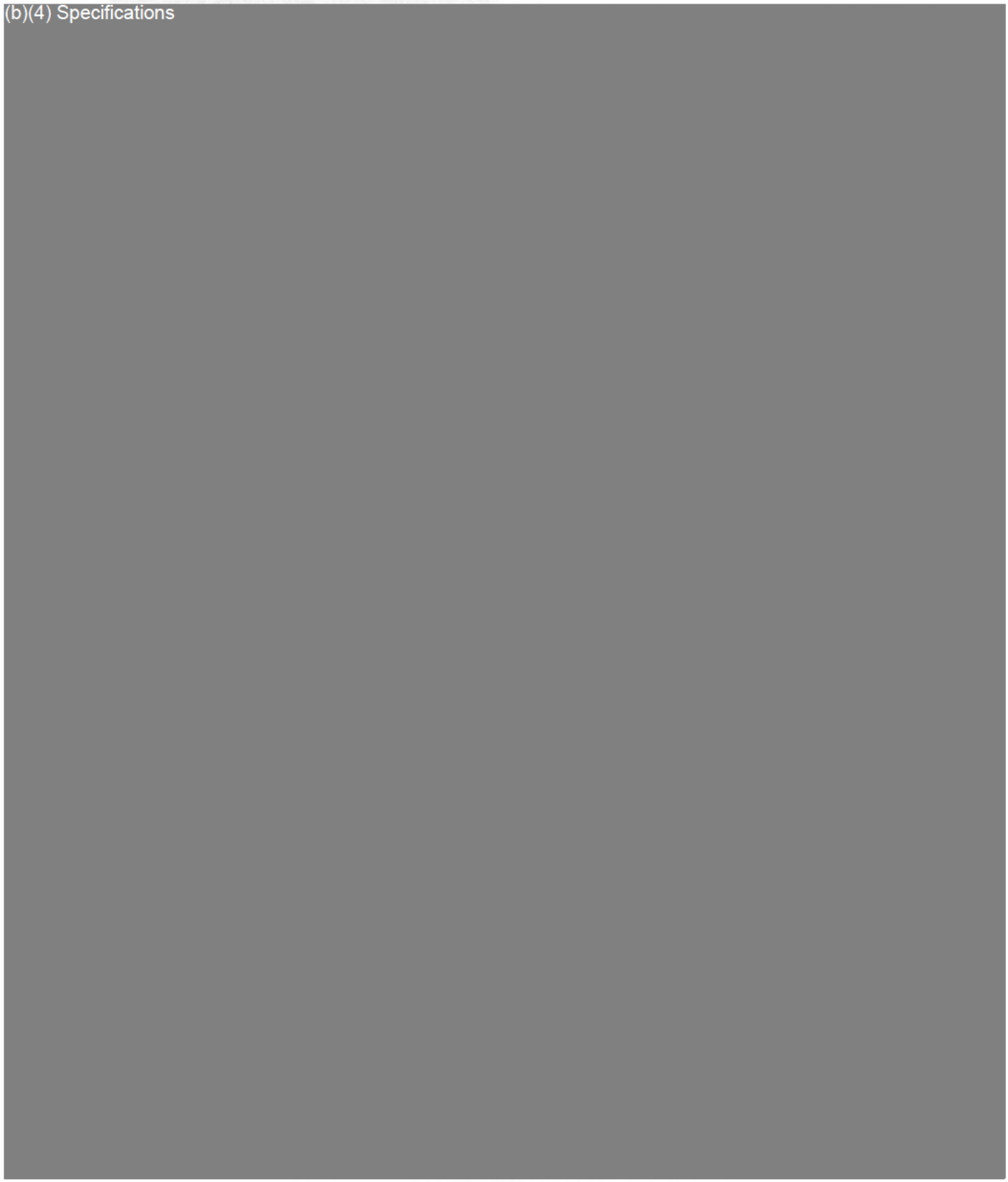
FDA Reviewer comments:
No deficiencies for sterilization. *This is acceptable.*

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SHELF LIFE

(b)(4) Specifications



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

[redacted]

LABELING

13.1 User Manual

LUOFUCON® Silver Foam Dressing Instruction for Use
RX Only
version: A/0
Product Name
LUOFUCON® Silver Foam Dressing
Description
"LUOFUCON® Silver Foam Dressing is a hydrophilic polymer with three-dimensional foam structure which is processed by frothing method of polyurethane. It can absorb exudates fast and excessively, retain exudates in-situ, and also maintain moist environment to accelerate healing process. LUOFUCON® Silver Foam Dressing does not stick to wound and it is painless removal. LUOFUCON® Silver Foam Dressing can restrain the bacteria growing and reduce infection. LUOFUCON® Silver Foam Dressing has been tested in vitro and found to be effective against bacteria such as Staphylococcus aureus, Enterococcus faecalis,

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Streptococcus pyogenes, Escherichia coli, Pseudomonsa aeruginosa and Klebsiella pneumoniae."

FDA Reviewer Comments:
The claims made in the labeling are not supported by the data provided in this submission. *This is not acceptable.*

The sponsor needs to remove the following claims from the labeling: "accelerate healing process" and "Luofucon Silver Foam Dressing can restrain the bacteria growing and reduce infection." or provide clinical data in order to support the claims made. In addition, in the instruction for use section there is no data in this submission that support the claim for use of the Luofucon Silver Foam Dressing for more than 72 hours (3 days). The sponsor needs to remove the 7 days claim and only claim what is supported by the data provided in this submission 72 hours (3 days).

RECOMMENDATION

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

[redacted]

Digital Signature Concurrence Table

Reviewer Sing-Off	Karoll J. Cortez Karoll J. Cortez -A 2014.09.18 15:38:58 -04'00'	September 17, 2014
Branch Chief Sign-Off	Elizabeth Claverie	September 17, 2014

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Premarket Notification [510(k)] Review

Traditional

K141619/S001

Date: September 18, 2014
To: The Record
From: Peter J. Yang, Ph.D.
Branch: Plastic and Reconstructive Surgery Branch II
Division: Division of Surgical Devices
Office: Office of Device Evaluation

Device Name: Luofucon Silver Foam Dressing
510(k) Holder: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Road, Dongjiang Hi-tec Industry Park
Huizhou, Guangdong 516005 China
Establishment Registration Number: 3007735241
Contact: Charles Shen
Official Correspondent, c/o Manton Business and Technology Services
853 Dorchester Ln, Unit-B
New Milford, NJ 07646
Phone: 608-217-9358
Fax: 425-930-2155
Email: cyshen@aol.com

TABLE OF CONTENTS

TABLE OF CONTENTS 1
I. Purpose of Submission and Document History 2
II. Document Summary 2
III. Recommendation 3
IV. Administrative Requirements 4
V. Device Description 4
Overview 4
Materials and Manufacturing 6
Product Release 7
VI. Indications for Use 8
VII. Predicate Device Comparison 9
VIII. Labeling 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

IX. Sterilization and Re-Use 12
X. Shelf Life and Stability Testing 12
XI. Biocompatibility 13
XII. Software 15
XIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety 15
XIV. Performance Testing – Bench 15
Density 15
Absorbency Test: Free Swell Absorption Capacity 15
Loss on Drying 16
pH 16
Silver Content 16
Antibacterial Activity 16
Determination of Minimum Effective Concentration 17
Silver Leachability 17
XV. Performance Testing – Animal 18
XVI. Performance Testing – Clinical 18
XVII. Deficiencies 18
XVIII. Substantial Equivalence Discussion 22
XIX. Contact History 23

I. Purpose of Submission and Document History

The 510(k) holder, Huizhou Foryou Medical Devices, would like to introduce the Luofucon Silver Foam Dressing into interstate commerce. The device is a family of four devices based off an open cell hydrophilic polyurethane foam dressing encapsulated with silver particles as an antimicrobial barrier with various backings.

K141619 (received June 17, 2014) was assigned to Peter Yang on June 18, 2014. The RTA checklist was completed on July 1, 2014 with an RTA1 decision. Supplement 001 (dated July 20, 2014) was received on June 23, 2014. The RTA checklist was completed with an RTAA recommendation on August 5, 2014 with branch concurrence on August 6, 2014. Consults were requested on August 7th, 2014 and received on September 18, 2014.

II. Document Summary

The device is a family of four devices based off an open cell hydrophilic polyurethane foam dressing encapsulated with silver particles as an antimicrobial barrier with various backings.

- The first model is the foam itself.
- The second model adds a polyurethane film as a backing which is the same area as the foam.
- The third model modifies the film to be larger in area than the foam, with a pressure sensitive adhesive to secure the dressing on the patient's skin.

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- The fourth model replaces the film in the third model with a non-woven material as the backing material, maintaining the same larger size with the pressure sensitive adhesive.

The Luofucon Silver Foam Dressing is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure sores
- Donor sites
- Surgical incisions
- Surgical excisions
- Burns (1st and 2nd degree)"

The predicate device is K110062, MediPlus-Foam AG Dressings. It is a family of polyurethane foam dressings with various polyurethane film backing layers. The silver component in the predicate device is a silver net, essentially a glass matrix with elemental silver embedded in the matrix. It is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: Ulcers (venous, arterial, diabetic); Pressure Sores; Donor Sites; Surgical Incisions; Surgical Excisions; Burns (1st and 2nd degree)." The indications for use for the subject device and the predicate device are identical.

A summary of the issues with the submission:

- The Sponsor claims, mostly in the labeling, that the device can reduce the infection in the wound. This statement is a Class III claim and should be substantiated with clinical data; moreover, it may be a drug claim warranting review jurisdiction transfer to CDER.
- It is unclear how much silver is contained in the device relative to the predicate device. The Sponsor has not compared the amount of silver.
- For most performance testing, only one sample of one lot was tested. The lack of triplicate testing extends to the shelf life and stability studies as well. The Sponsor should perform testing on three lots of devices, with multiple samples within each lot tested.
- For most performance testing, only one sample was tested – the first variant of the device, namely, the foam dressing itself. Other variants of the dressing, including those with additional layers of PET film and/or non-woven fabric layers, were not tested. The Sponsor should justify the use of the foam as the representative sample.
- Complete test reports for the performance tests are not provided.
- Labeling implies that the device may be left on the wound for more than 7 days without a clinical risk analysis to justify this labeling statement.

Thus, additional information from the Sponsor is required.

III. Recommendation

Request for additional information

Regulation Number: 21 CFR §

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO

IV. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if Prescription or OTC)	x			prescription
Truthful and Accurate Statement	x			
510(k) Summary or 510(k) Statement	x			
ClinicalTrials.gov Form FDA-3874			x	
Standards Form	x			Form 3654

V. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	
Are "cleaning" instructions included for the end user?			x

Overview

The device is a family of four devices that are all based on a "sterile, highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable polyurethane foam encapsulated with silver particles as an antimicrobial barrier" (S1/Section 11 p. 2).

The basic model is the foam itself.

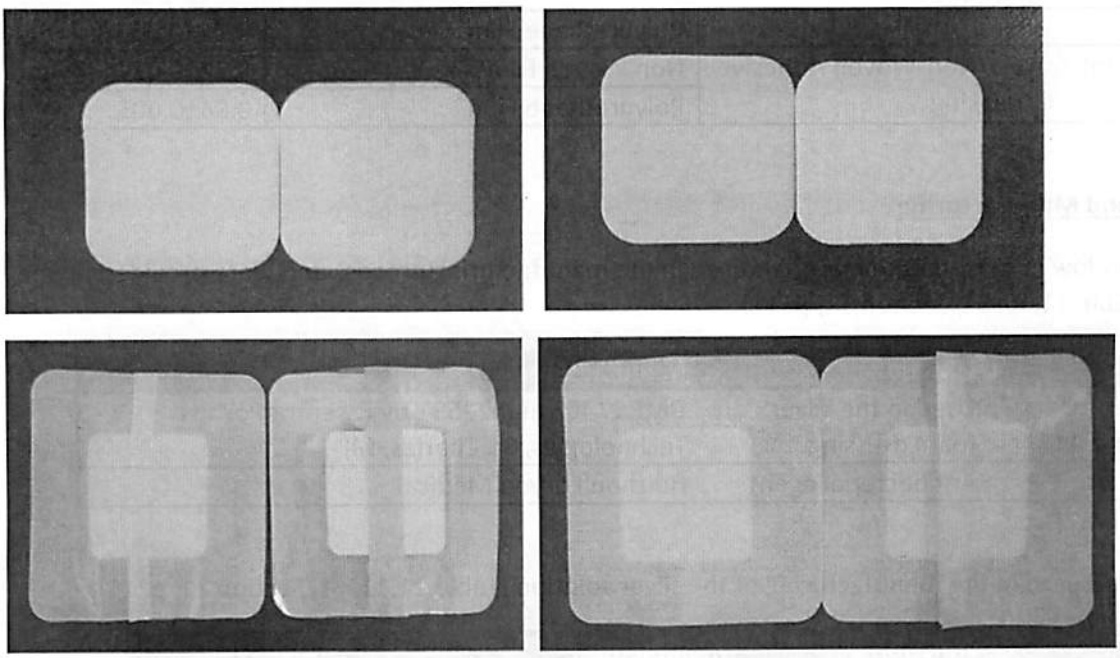
The second variant described has an additional layer (25 ± 5 µm) of "non porous breathable polyurethane film (backing film)" laminated to the foam dressing. Both the film and the foam have the same surface area; this film is described as having a "cosmetic purpose."

The third variant described laminates a 40 ± 5 µm thick polyurethane film layer to the foam. Then a third layer of 40 ± 5 µm thick poly(ethylene terephthalate) (PET) film with a pressure sensitive adhesive is layered on top to provide a method for sticking the dressing on skin.

The fourth variant described is similar to the third variant. Instead of the third layer of PET film, a 280 ± 20 µm thick film of a "non-woven" material with a pressure sensitive adhesive is layered on top. This material is formed from "viscose rayon fiber and PET fiber." The non-woven material is claimed to be both "waterproof and semi permeable."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The adhesive used in the third and fourth variants is 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

For the first and second variants, the sizes described are:

50 x 50 x 3 mm	50 x 50 x 5 mm
75 x 75 x 3 mm	75 x 75 x 5 mm
100 x 100 x 3 mm	100 x 100 x 5 mm
120 x 100 x 3 mm	120 x 100 x 5 mm
120 x 120 x 3 mm	120 x 120 x 5 mm
150 x 100 x 3 mm	150 x 100 x 5 mm
150 x 150 x 3 mm	150 x 150 x 5 mm
200 x 100 x 3 mm	200 x 100 x 5 mm
200 x 150 x 3 mm	200 x 150 x 5 mm

For the third and fourth variants, the sizes described are:

Adhesive area: 50 x 50 mm	Foam: 20 x 20 x 3 mm	Foam: 20 x 20 x 5 mm
Adhesive area: 100 x 60 mm	Foam: 60 x 30 x 3 mm	Foam: 60 x 30 x 5 mm
Adhesive area: 100 x 100 mm	Foam: 50 x 50 x 3 mm	Foam: 50 x 50 x 5 mm
Adhesive area: 150 x 150 mm	Foam: 100 x 100 x 3 mm	Foam: 100 x 100 x 5 mm
Adhesive area: 180 x 180 mm	Foam: 110 x 110 x 3 mm	Foam: 110 x 110 x 5 mm

A summary table was provided by the Sponsor (S1/Section 11, p. 9, Table 11.5):

Variant	Description	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Materials and Manufacturing

(b)(4) Specifications

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(b)(4) Specifications

VI. Indications for Use

The Sponsor provided this table in their Substantial Equivalence discussion (Section 12, p. 1). Only the indications are listed here (see Predicate Device Comparison section below for further discussion).

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same

Reviewer comment: The indications are identical.

In addition to the Indications for Use, multiple claims are also presented throughout the submission, particularly in the Device Description and in the Labeling sections. For labeling claims, please see the Labeling section of this memo.

In Section 11, Device Description, the following claims are made about the device:

- 11.1, p. 2: "The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms."
- 11.1, p. 2: "Odour reduction results from the antibacterial effect in the dressing."

Reviewer comment: The second claim is also present in the 510(k) Summary. Both claims are problematic. The first claim should be more strictly defined as acting as a barrier to infection. As stated, it implies that the dressing can potentially protect the wound from bacteria/microorganism growth within the wound itself, which is a claim based on the chemical action of the silver. Thus, CDER could have review jurisdiction. The second claim is not substantiated by any testing, and it is unclear what the mechanism of action is for the odor reduction itself.

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Deficiency: Sponsor should remove statements regarding the implication of reduction of infection within the wound. Sponsor should provide a mechanism of action for the claim regarding "odour reduction" and substantiate this claim with performance testing. Alternatively, they may remove this statement from their labeling.

VII. Predicate Device Comparison

The Sponsor provided this table in their Substantial Equivalence section (Section 12, p. 1-2):

Description	Our Device	Predicate Device 1 (K110062)
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days a
Single Use	Yes	Yes
Sterile	Sterile	Sterile

With regard to similarities, the Sponsor states (Section 12, p. 2) that both devices use silver and that both devices use polyurethane foam for "exudate absorption and wound management."

With regard to differences, the Sponsor states (Section 12, p. 2) that the predicate device uses a "multi-layered polyurethane structure," while the subject device uses either a single layered or double layered structure.

Reviewer comment: With regard to minor differences in the foam structure, this reviewer concurs.

The predicate device is K110062, MediPurpose MediPlus-Foam Ag Dressings. It is actually a family of devices submitted by MediPurpose Ltd. There are multiple forms of devices (drawing from the reviewer memo for K110062, authored by Sam Arepalli, PhD, PRSB2):

- MediPlus-Foam Ag: a "multi-layered, sterile highly absorbing open cell hydrophilic wound dressing composed of a thick, soft, smooth, elastic and breathable polyurethane (PU) foam sandwiched in between a breathable PU film and a silver net layer acting as an antimicrobial barrier."
- MediPlus-SuperFoam Ag: Thicker foam layer that is easier to bend
- MediPlus-ComfortFoam Ag: Foam dressing stuck to a breathable PU film coated in adhesive. Silver net layer remains on the bottom.

In S1 of the predicate K110062 submission, the Sponsor states that the silver net layer is composed of silver metal that has been immobilized or incorporated into a glass matrix ("Bactiglas"). The dressing is stated to contain 79 ppm of elemental silver.

Reviewer comment: Both devices are made of polyurethane foam. The subject device is similar to the predicate devices in terms of having additional variants with a variety of backing films.

However, the devices are not comparable in how the silver is incorporated, and thus, how the silver is released. Although both devices use metallic silver, it is unclear how the silver in the predicate device is incorporated into the formulation. From the 510(k) Summary for K110062, there is no

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mention of the method by which silver is incorporated in the device, other than the statement that "the silver ions are incorporated in the dressing". In the subject device, the foam is polymerized and created in the presence of oligomer-encapsulated silver nanoparticles, whereas in the predicate device, the silver is part of a separate layer that presumably contacts the wound.

Also, while the predicate device contains 79 ppm of elemental silver, this does not provide sufficient information to compute the total silver in a given size of predicate dressing. Meanwhile, the subject device contains approximately 3 µg/cm3 silver, which for the highest size of dressing (200 x 150 x 5 mm = 150 cm3) = 450 µg silver. It is not clear how the silver content compares between the two dressings. For reference, the Luofucon Silver PU Antibacterial Foam Dressing (K140954, at the time of this writing on hold due to an AI letter) contains 45 mg silver for the same area of foam, 100 times the amount in the subject device.

Deficiency: The Sponsor does not address the differences in silver content. They should compare the total amount of silver and provide a justification for the change in the silver content of the subject device.

VIII. Labeling

The Sponsor provided labeling in Section 13 of Supplement 001. Packaging for the immediate device, as well as box packaging and the package insert, was included.

General Labeling Checklist			
Label		**Instructions for Use**	
Company name & address	Yes	Company name, address, and contact info	Yes
System/component name	n/a	System name	n/a
Material	**No**	Device description	Yes
Part/lot number	Yes	Material	Yes
Single use statement	Yes	Indications for use	Yes
Sterile notation	Yes	Single use statement	Yes
Expiration date	Yes	Sterile notation	Yes
"See package insert" statement	**No**	Contraindications, warnings, precautions	Yes
Cautionary symbol restricting sale to a physician	Yes	Cautionary symbol restricting sale to a physician	Yes
Explanatory text to accompany symbols	Yes	Explanatory text to accompany symbols	n/a

Deficiency: Sponsor should add a statement to the immediate package labeling to see the package insert for complete Instructions for Use.

Deficiency: Sponsor should include the materials of composition of the device on all labeling, including the components of the film.

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Deficiency: Sponsor should make the following changes to their package labeling:
For each dressing size, please state the total maximum amount of silver in the dressing.
Please remove statements of "% reduction." Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 7 days in vitro against the following bacteria: (mention the names of each strain tested)."
Please prominently display/state that silver is present as a preservative within the dressing.
Please include this statement in your 510(k) Summary and your labeling. You may wish to also add this statement to your Indications for Use.
You may wish to consider indicating how long the device should be used overall over multiple dressing changes.
Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

Reviewer comment: The above deficiencies were also communicated to the Sponsor for their own K140954, Silver PU Antibacterial Foam Dressing, which at the time of this review is still on hold pending AI.

The Sponsor added several claims in their labeling, including:

- "It can... maintain moist environment to accelerate the healing process."
- "LUOFUCON Silver Foam Dressing can restrain the bacteria growing and reduce infection."
- "LUOFUCON Silver Foam Dressing has been tested in vitro and found to be effective against bacteria such as Staph..."
- "Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates."
- "The device is non-irritating, non-sensitising, non-cyctotoxic [sic] and biocompatible in a wound environment."
- The package labeling includes an "Adverse Reactions" section that details the biocompatibility testing performed on the device.

Deficiency: These additional labeling claims should be addressed.
The claim regarding "accelerating the healing process" implies that the dressing actively promotes wound healing and should be substantiated by clinical data in a PMA.
The claim regarding the reduction of infection is a drug claim (as the mechanism would presumably be through the release of silver ions) and so would lead to questions of product jurisdiction, i.e. whether CDER should review the device. The Sponsor should remove this statement and indicate that the silver is present to inhibit bacterial colonization within the dressing only.
The main issue with the description of bacteria is the term "such as." The Sponsor should only state those bacteria which their device has been shown to be effective against.
The labeling states that the dressing may be left on a patient for 7 days. This may lead a patient to assume that the silver lasts for 7 days, when the antibacterial effect only lasts for 3. The Sponsor should limit the amount of time that the device should remain on a patient to 3 days.

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The last two statements imply that the Sponsor has conducted initial testing above and beyond what is needed to demonstrate substantial equivalence for the purposes of FDA clearance. These statements should be removed.

In the "Warnings" section of the package insert, the Sponsor states that the device "is intended for short-term use up to 28 days." This length of time of leaving the device on a patient is not supported by their current submission.

Deficiency: The Sponsor should provide a justification for the length of time that this device should be used for. If multiple dressing changes are expected, the Sponsor should discuss the risk of repeated exposure to silver.

IX. Sterilization and Re-Use

Sterility and shelf life information is provided in Section 14.

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam (moist heat), EO, Radiation):	EO	
b. Dose, for radiation (e.g., 25 – 50 kGy):	n/a	
c. Sterilant residuals remaining on the device:	0.27 mg EO; 2 mg/day max 6.75 mg ECH; 2 mg/day max	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	ISO 11135-1:2007 Validation: Half-cycle approach (Annex B)	
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		No
If so, a description of the method: (e.g., LAL (Limulus Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	Immediate packaging: "enforced" paper – plastic pouch; heat sealed, 1 pc/pouch Intermediate packaging: Paper box Outer packaging: Corrugated board carton	

X. Shelf Life and Stability Testing

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(b)(4) Specifications

XI. Biocompatibility

(b)(4) Specifications

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(b)(4) Specifications

XII. Software

Not applicable to this device.

XIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable to this device.

XIV. Performance Testing – Bench

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

XV. Performance Testing – Animal

No animal data were provided.

XVI. Performance Testing – Clinical

Not applicable to this device.

XVII. Deficiencies

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

[redacted]

XVIII. Substantial Equivalence Discussion

	YES	NO	
1. Is the predicate device legally marketed?	X		If **YES** = Go to 2 If **NO** = Stop **NENO**
2. Do the devices have the same intended use? • Review labeling to assure consistency w/ IFU form and 510(k) Summary. • Note that performance data can occasionally be used to determine if a different indication does or does not create a different intended use.	X		If **YES** = Go to 3 If **NO** = Stop **AINE** or **NENI**
3. Do the devices have the same technological characteristics? • Note that this question should be interpreted narrowly. • Unless the subject device is practically identical to a predicate, answer 'no' to this question.		X	If **YES** = Stop **SESE** If **NO** = Go to 4

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4. Do the different technological characteristics raise different S&E questions?		X	If **YES** = Stop **AINE or NENQ** If **NO** = Go to 5a
5a. Are methods available to evaluate the different technological characteristics?	X		If **YES** = continue If **NO** = Stop **NSE**
Are all necessary performance data available for review?		X	If **YES** = Go to If **NO** = Stop **AINN**
5b. Do the data demonstrate substantial equivalence?			If **YES** = Stop **SESE** If **NO** = Stop **NENL**

XIX. Contact History

- June 18, 2014: K141619 assigned to Peter Yang
- July 1, 2014: RTA refusal email automatically sent
- July 25, 2014: K141619/S001 assigned to Peter Yang
- August 6, 2014: RTA acceptance email automatically sent

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter Yang -S 2014.09.18 17:53:57 -04'00'
Branch Chief Sign-Off	Jiyoung Dang -S 2014.09.19 06:50:00 -04'00'
Division Sign-Off	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Premarket Notification [510(k)] Review

Traditional

K141619/S002

Date: January 30, 2015
To: The Record
From: Peter J. Yang, Ph.D.
Branch: Plastic and Reconstructive Surgery Branch II
Division: Division of Surgical Devices
Office: Office of Device Evaluation

Device Name: Luofucon Silver Foam Dressing
510(k) Holder: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Road, Dongjiang Hi-tec Industry Park
Huizhou, Guangdong 516005 China
Establishment Registration Number: 3007735241
Contact: Charles Shen
Official Correspondent, c/o Manton Business and Technology Services
853 Dorchester Ln, Unit-B
New Milford, NJ 07646
Phone: 608-217-9358
Fax: 425-930-2155
Email: cyshen@aol.com

TABLE OF CONTENTS

TABLE OF CONTENTS 1
I. Purpose of Submission and Document History 2
II. Document Summary 2
III. Recommendation 4
IV. Administrative Requirements 4
V. Device Description 4
Overview 5
Materials and Manufacturing 6
Product Release 7
VI. Indications for Use 8
VII. Predicate Device Comparison 9
VIII. Labeling 10

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8730; Released by CDRH on 4/4/2018

IX. Sterilization and Re-Use 12
X. Shelf Life and Stability Testing 13
XI. Biocompatibility 13
XII. Software 15
XIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety 15
XIV. Performance Testing – Bench 15
Density 15
Absorbency Test: Free Swell Absorption Capacity 15
Loss on Drying 15
pH 16
Silver Content 16
Antibacterial Activity 16
Determination of Minimum Effective Concentration 17
Silver Leachability 17
XV. Performance Testing – Animal 18
XVI. Performance Testing – Clinical 18
XVII. Deficiencies and Response (S2) 18
XVIII. Antibacterial Protocol Review (S2) 25
XIX. Deficiencies for Second Hold 26
XX. Substantial Equivalence Discussion 27
XXI. Contact History 28

I. Purpose of Submission and Document History

The 510(k) holder, Huizhou Foryou Medical Devices, would like to introduce the Luofucon Silver Foam Dressing into interstate commerce. The device is a family of four devices based off an open cell hydrophilic polyurethane foam dressing encapsulated with silver particles as an antimicrobial barrier with various backings.

K141619 (received June 17, 2014) was assigned to Peter Yang on June 18, 2014. The RTA checklist was completed on July 1, 2014 with an RTA1 decision. Supplement 001 (dated July 20, 2014) was received on June 23, 2014. The RTA checklist was completed with an RTAA recommendation on August 5, 2014 with branch concurrence on August 6, 2014. Consults were requested on August 7th, 2014 and received on September 18, 2014. An AI letter was issued for K141619/S001 on September 21, 2014. The response from the Sponsor, the subject of this submission, was received on January 14, 2015.

II. Document Summary

The device is a family of four devices based off an open cell hydrophilic polyurethane foam dressing encapsulated with silver particles as an antimicrobial barrier with various backings.

- The first model is the foam itself.
- The second model adds a polyurethane film as a backing which is the same area as the foam.

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- The third model modifies the film to be larger in area than the foam, with a pressure sensitive adhesive to secure the dressing on the patient's skin.
- The fourth model replaces the film in the third model with a non-woven material as the backing material, maintaining the same larger size with the pressure sensitive adhesive.

The Luofucon Silver Foam Dressing is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure sores
- Donor sites
- Surgical incisions
- Surgical excisions
- Burns (1st and 2nd degree)"

The predicate device is K110062, MediPlus-Foam AG Dressings. It is a family of polyurethane foam dressings with various polyurethane film backing layers. The silver component in the predicate device is a silver net, essentially a glass matrix with elemental silver embedded in the matrix. It is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: Ulcers (venous, arterial, diabetic); Pressure Sores; Donor Sites; Surgical Incisions; Surgical Excisions; Burns (1st and 2nd degree)." The indications for use for the subject device and the predicate device are identical.

A summary of the issues with Supplement 1:

- The Sponsor claims, mostly in the labeling, that the device can reduce the infection in the wound. This statement is a Class III claim and should be substantiated with clinical data; moreover, it may be a drug claim warranting review jurisdiction transfer to CDER.
- It is unclear how much silver is contained in the device relative to the predicate device. The Sponsor has not compared the amount of silver.
- For most performance testing, only one sample of one lot was tested. The lack of triplicate testing extends to the shelf life and stability studies as well. The Sponsor should perform testing on three lots of devices, with multiple samples within each lot tested.
- For most performance testing, only one sample was tested – the first variant of the device, namely, the foam dressing itself. Other variants of the dressing, including those with additional layers of PET film and/or non-woven fabric layers, were not tested. The Sponsor should justify the use of the foam as the representative sample.
- Complete test reports for the performance tests are not provided.
- Labeling implies that the device may be left on the wound for more than 7 days without a clinical risk analysis to justify this labeling statement.

Thus, additional information from the Sponsor was requested on September 19, 2014. The Sponsor provided a response on January 14, 2015 (dated January 10, 2015). A consult was issued to Brandon Kitchel, PRSB2 reviewer and microbiologist, on January 14, 2015, and was received on January 23, 2015. The consult identified new issues with the antibacterial testing that were not identified Supplement 001. **Review of Supplement 002 begins in Section XVII.** Please note the detailed connection with K140954/S002, a submission from the same Sponsor. To summarize the noted issues:

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- The antibacterial testing protocol was originally misread to mean that bacteria contacted the dressing for 3 days. Instead, the dressing was conditioned with a small amount of cell culture medium for 3 days, followed by inoculation and incubation for 24 hours. Thus, all of the bacterial testing only tests for 24 hours of effectiveness.
- Bacteria are combined with hot agar for counting. However, the temperature of the agar is likely to kill much of the bacteria. The testing should be redone with cooled agar plates.
- Packaging integrity test reports were not provided, but the Sponsor stated they were.
- The Sponsor did not correct an issue with the labeling (describing biocompatibility testing on the labeling as if the biocompatibility testing was above and beyond what was needed for clearance).
- Symbols in the labeling should be accompanied by explanatory text.

Hence, the file should be put on a second hold.

III. Recommendation

Request for additional information

Regulation Number: 21 CFR §
Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO

IV. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if Prescription or OTC)	x			prescription
Truthful and Accurate Statement	x			
510(k) Summary or 510(k) Statement	x			
ClinicalTrials.gov Form FDA-3874			x	
Standards Form	x			Form 3654

V. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	
Are "cleaning" instructions included for the end user?			x

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Overview

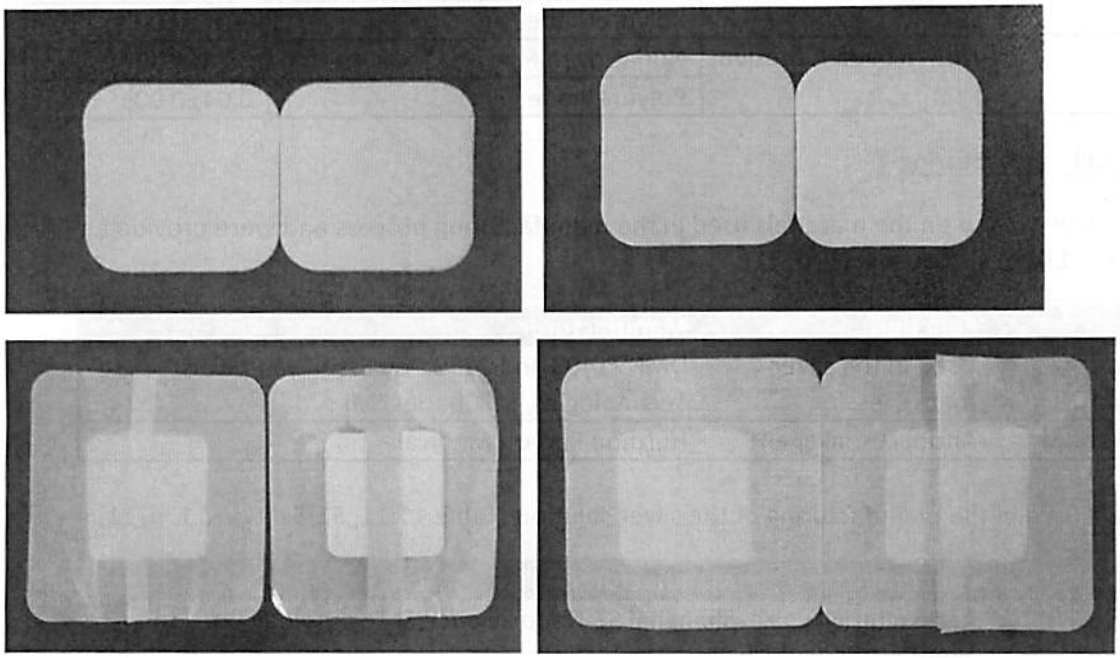
The device is a family of four devices that are all based on a "sterile, highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable polyurethane foam encapsulated with silver particles as an antimicrobial barrier" (S1/Section 11 p. 2).

The basic model is the foam itself.

The second variant described has an additional layer (25 ± 5 µm) of "non porous breathable polyurethane film (backing film)" laminated to the foam dressing. Both the film and the foam have the same surface area; this film is described as having a "cosmetic purpose."

The third variant described laminates a 40 ± 5 µm thick polyurethane film layer to the foam. Then a third layer of 40 ± 5 µm thick poly(ethylene terephthalate) (PET) film with a pressure sensitive adhesive is layered on top to provide a method for sticking the dressing on skin.

The fourth variant described is similar to the third variant. Instead of the third layer of PET film, a 280 ± 20 µm thick film of a "non-woven" material with a pressure sensitive adhesive is layered on top. This material is formed from "viscose rayon fiber and PET fiber." The non-woven material is claimed to be both "waterproof and semi permeable."



The adhesive used in the third and fourth variants is 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

For the first and second variants, the sizes described are:

50 x 50 x 3 mm	50 x 50 x 5 mm
75 x 75 x 3 mm	75 x 75 x 5 mm
100 x 100 x 3 mm	100 x 100 x 5 mm
120 x 100 x 3 mm	120 x 100 x 5 mm
120 x 120 x 3 mm	120 x 120 x 5 mm

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150 x 100 x 3 mm	150 x 100 x 5 mm
150 x 150 x 3 mm	150 x 150 x 5 mm
200 x 100 x 3 mm	200 x 100 x 5 mm
200 x 150 x 3 mm	200 x 150 x 5 mm

For the third and fourth variants, the sizes described are:

Adhesive area: 50 x 50 mm	Foam: 20 x 20 x 3 mm
Adhesive area: 100 x 60 mm	Foam: 60 x 30 x 3 mm
Adhesive area: 100 x 100 mm	Foam: 50 x 50 x 3 mm
Adhesive area: 150 x 150 mm	Foam: 100 x 100 x 3 mm
Adhesive area: 180 x 180 mm	Foam: 110 x 110 x 3 mm

Foam: 20 x 20 x 5 mm
Foam: 60 x 30 x 5 mm
Foam: 50 x 50 x 5 mm
Foam: 100 x 100 x 5 mm
Foam: 110 x 110 x 5 mm

A summary table was provided by the Sponsor (S1/Section 11, p. 9, Table 11.5):

Variant	Description	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Materials and Manufacturing

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

VI. Indications for Use

The Sponsor provided this table in their Substantial Equivalence discussion (Section 12, p. 1). Only the indications are listed here (see Predicate Device Comparison section below for further discussion).

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same

Reviewer comment: The indications are identical.

In addition to the Indications for Use, multiple claims are also presented throughout the submission, particularly in the Device Description and in the Labeling sections. For labeling claims, please see the Labeling section of this memo.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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In Section 11, Device Description, the following claims are made about the device:

- 11.1, p. 2: "The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms."
- 11.1, p. 2: "Odour reduction results from the antibacterial effect in the dressing."

Reviewer comment: The second claim is also present in the 510(k) Summary. Both claims are problematic. The first claim should be more strictly defined as acting as a barrier to infection. As stated, it implies that the dressing can potentially protect the wound from bacteria/microorganism growth within the wound itself, which is a claim based on the chemical action of the silver. Thus, CDER could have review jurisdiction. The second claim is not substantiated by any testing, and it is unclear what the mechanism of action is for the odor reduction itself.

Deficiency: Sponsor should remove statements regarding the implication of reduction of infection within the wound. Sponsor should provide a mechanism of action for the claim regarding "odour reduction" and substantiate this claim with performance testing. Alternatively, they may remove this statement from their labeling.

VII. Predicate Device Comparison

The Sponsor provided this table in their Substantial Equivalence section (Section 12, p. 1-2):

Description	Our Device	Predicate Device 1 (K110062)
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days a
Single Use	Yes	Yes
Sterile	Sterile	Sterile

With regard to similarities, the Sponsor states (Section 12, p. 2) that both devices use silver and that both devices use polyurethane foam for "exudate absorption and wound management."

With regard to differences, the Sponsor states (Section 12, p. 2) that the predicate device uses a "multi-layered polyurethane structure," while the subject device uses either a single layered or double layered structure.

Reviewer comment: With regard to minor differences in the foam structure, this reviewer concurs.

The predicate device is K110062, MediPurpose MediPlus-Foam Ag Dressings. It is actually a family of devices submitted by MediPurpose Ltd. There are multiple forms of devices (drawing from the reviewer memo for K110062, authored by Sam Arepalli, PhD, PRSB2):

- MediPlus-Foam Ag: a "multi-layered, sterile highly absorbing open cell hydrophilic wound dressing composed of a thick, soft, smooth, elastic and breathable polyurethane (PU) foam sandwiched in between a breathable PU film and a silver net layer acting as an antimicrobial barrier."
- MediPlus-SuperFoam Ag: Thicker foam layer that is easier to bend

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- **MediPlus-ComfortFoam Ag: Foam dressing stuck to a breathable PU film coated in adhesive. Silver net layer remains on the bottom.**

In S1 of the predicate K110062 submission, the Sponsor states that the silver net layer is composed of silver metal that has been immobilized or incorporated into a glass matrix ("Bactiglas"). The dressing is stated to contain 79 ppm of elemental silver.

> **Reviewer comment: Both devices are made of polyurethane foam. The subject device is similar to the predicate devices in terms of having additional variants with a variety of backing films.**
>
> **However, the devices are not comparable in how the silver is incorporated, and thus, how the silver is released. Although both devices use metallic silver, it is unclear how the silver in the predicate device is incorporated into the formulation. From the 510(k) Summary for K110062, there is no mention of the method by which silver is incorporated in the device, other than the statement that "the silver ions are incorporated in the dressing". In the subject device, the foam is polymerized and created in the presence of oligomer-encapsulated silver nanoparticles, whereas in the predicate device, the silver is part of a separate layer that presumably contacts the wound.**
>
> **Also, while the predicate device contains 79 ppm of elemental silver, this does not provide sufficient information to compute the total silver in a given size of predicate dressing. Meanwhile, the subject device contains approximately 3 µg/cm3 silver, which for the highest size of dressing (200 x 150 x 5 mm = 150 cm3) = 450 µg silver. It is not clear how the silver content compares between the two dressings. For reference, the Luofucon Silver PU Antibacterial Foam Dressing (K140954, at the time of this writing on hold due to an AI letter) contains 45 mg silver for the same area of foam, 100 times the amount in the subject device.**

> **Deficiency: The Sponsor does not address the differences in silver content. They should compare the total amount of silver and provide a justification for the change in the silver content of the subject device.**

VIII. Labeling

The Sponsor provided labeling in Section 13 of Supplement 001. Packaging for the immediate device, as well as box packaging and the package insert, was included.

General Labeling Checklist			
Label		**Instructions for Use**	
Company name & address	Yes	Company name, address, and contact info	Yes
System/component name	n/a	System name	n/a
Material	**No**	Device description	Yes
Part/lot number	Yes	Material	Yes
Single use statement	Yes	Indications for use	Yes
Sterile notation	Yes	Single use statement	Yes
Expiration date	Yes	Sterile notation	Yes
"See package insert" statement	**No**	Contraindications, warnings, precautions	Yes
Cautionary symbol restricting sale to a physician	Yes	Cautionary symbol restricting sale to a physician	Yes

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Explanatory text to accompany symbols	Yes	Explanatory text to accompany symbols	n/a

Deficiency: Sponsor should add a statement to the immediate package labeling to see the package insert for complete Instructions for Use.

Deficiency: Sponsor should include the materials of composition of the device on all labeling, including the components of the film.

Deficiency: Sponsor should make the following changes to their package labeling:
For each dressing size, please state the total maximum amount of silver in the dressing.
Please remove statements of "% reduction." Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 7 days in vitro against the following bacteria: (mention the names of each strain tested)."
Please prominently display/state that silver is present as a preservative within the dressing.
Please include this statement in your 510(k) Summary and your labeling. You may wish to also add this statement to your Indications for Use.
You may wish to consider indicating how long the device should be used overall over multiple dressing changes.
Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

Reviewer comment: The above deficiencies were also communicated to the Sponsor for their own K140954, Silver PU Antibacterial Foam Dressing, which at the time of this review is still on hold pending AI.

The Sponsor added several claims in their labeling, including:

- "It can... maintain moist environment to accelerate the healing process."
- "LUOFUCON Silver Foam Dressing can restrain the bacteria growing and reduce infection."
- "LUOFUCON Silver Foam Dressing has been tested in vitro and found to be effective against bacteria such as Staph..."
- "Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates."
- "The device is non-irritating, non-sensitising, non-cyctotoxic [sic] and biocompatible in a wound environment."
- The package labeling includes an "Adverse Reactions" section that details the biocompatibility testing performed on the device.

Deficiency: These additional labeling claims should be addressed.
The claim regarding "accelerating the healing process" implies that the dressing actively promotes wound healing and should be substantiated by clinical data in a PMA.
The claim regarding the reduction of infection is a drug claim (as the mechanism would presumably be through the release of silver ions) and so would lead to questions of product jurisdiction, i.e. whether CDER should review the device. The Sponsor should remove this

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statement and indicate that the silver is present to inhibit bacterial colonization within the dressing only.
The main issue with the description of bacteria is the term "such as." The Sponsor should only state those bacteria which their device has been shown to be effective against.
The labeling states that the dressing may be left on a patient for 7 days. This may lead a patient to assume that the silver lasts for 7 days, when the antibacterial effect only lasts for 3. The Sponsor should limit the amount of time that the device should remain on a patient to 3 days.
The last two statements imply that the Sponsor has conducted initial testing above and beyond what is needed to demonstrate substantial equivalence for the purposes of FDA clearance. These statements should be removed.

In the "Warnings" section of the package insert, the Sponsor states that the device "is intended for short-term use up to 28 days." This length of time of leaving the device on a patient is not supported by their current submission.

Deficiency: The Sponsor should provide a justification for the length of time that this device should be used for. If multiple dressing changes are expected, the Sponsor should discuss the risk of repeated exposure to silver.

IX. Sterilization and Re-Use

Sterility and shelf life information is provided in Section 14.

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam (moist heat), EO, Radiation):	EO	
b. Dose, for radiation (e.g., 25 – 50 kGy):	n/a	
c. Sterilant residuals remaining on the device:	0.27 mg EO; 2 mg/day max 6.75 mg ECH; 2 mg/day max	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	ISO 11135-1:2007 Validation: Half-cycle approach (Annex B)	
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		No
If so, a description of the method: (e.g., LAL (Limulus Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	Immediate packaging: "enforced" paper – plastic pouch; heat sealed, 1 pc/pouch Intermediate packaging: Paper box Outer packaging: Corrugated board carton	

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X. Shelf Life and Stability Testing

(b)(4) Specifications

XI. Biocompatibility

(b)(4) Specifications

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(b)(4) Specifications

XII. Software

Not applicable to this device.

XIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable to this device.

XIV. Performance Testing – Bench

(b)(4) Specifications

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(b)(4) Specifications

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The antibacterial testing that was conducted was reviewed by Dr. Karoll Cortez, MD, reviewer in the Infection Control Devices Branch (INCB). Dr. Cortez's comments are included in the deficiencies below, primarily in Deficiency 4.

> **Reviewer comment:** To summarize, the protocol, while providing copious information, is nevertheless poorly documented, and is difficult to understand. Moreover, the claims that were scattered throughout the submission concerning the device's ability to reduce infection in the wound (please see Labeling section for several such examples) was also highlighted. It is also unclear how and when antibacterial testing was conducted with samples designated for substantiating shelf life.

Determination of Minimum Effective Concentration

Section 18.7 (Section 18, p. 21): The Sponsor tested three concentrations of silver: 1.35, 2.20, and 3.0 (evaluated to actually be 2.85) µg/cm3. The Sponsor only used Pseudomonas aeruginosa and Staphylococcus aureus to calculate the MEC. At 2.20 µg/cm3, the dressing achieved a 4 log reduction in both bacterial species. The Sponsor states that "the Minimum Effective Concentration for the device is determined to be between 1.35 and 2.20 µg/cm3, most likely to be a little more than 1.35 µg/cm3."

This testing was apparently not reviewed by Dr. Karoll Cortez, MD, INCB reviewer.

> **Reviewer comment:** To summarize, the issue here is that the MEC is stated "to be a little more than 1.35 µg/cm3." As only 2.20 µg/cm3 was tested, 2.20 µg/cm3 should be the MEC.

Silver Leachability

Section 18.8 (Section 18, p. 25): The Sponsor placed a single 100 x 100 x 3 mm foam dressing in 20 mL of simulated wound fluid. Simulated wound fluid was created from 10% porcine serum and 90% phosphate buffered saline. At 24, 48, and 72 hours, fluid was removed from the device and another 20 mL of fluid was added to the device to replace what was removed. Calculated as a percentage of the total theoretical silver in the device, the device leached 33.3%, 55.3%, and 72.0% over 24, 48, and 72 hours, respectively.

Based on the conclusions regarding this test, namely that 72.0% of the silver is released after three days, the Sponsor states that 2.2 µg/cm3 "will be shown in product label as estimated release amount to the patient after device use. Compared to other products in the market, our silver foam dressing has relatively low silver release, therefore causing much less skin discoloration effect."

> **Reviewer comment:** There are a number of issues with this test. The analytical method is acceptable. However, there are a number of concerns:
> * It is unclear why the 100 x 100 x 3 mm sample was immersed in only 20 mL of simulated wound fluid. The device can absorb (100 x 100 x 3 mm) * 0.11 g/cm3 [density] * 13.8 g/g [free swell absorptive capacity] = 45.54 g of fluid, or approximately 45 mL. Given that the fluid is clearly not permeating the entire mass of product, not all of the silver may be removed.
> * The method for this test is unclear, as with the other tests.
> * The Sponsor should not state that the 2.2 µg/cm3 value will be shown as the estimated release. The total silver content should be shown and no more. The 2.2 µg/cm3 is a minimum, not a maximum (as would be expected by labeling the device's estimated silver release as such).

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

XV. Performance Testing – Animal

No animal data were provided.

XVI. Performance Testing – Clinical

Not applicable to this device.

XVII. Deficiencies and Response (S2)

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

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(b)(4) Specifications

[redacted]

XX. Substantial Equivalence Discussion

	YES	NO	
1. Is the predicate device legally marketed?	X		If **YES** = Go to 2 If **NO** = Stop **NENO**
2. Do the devices have the same intended use? • Review labeling to assure consistency w/ IFU form and 510(k) Summary. • Note that performance data can occasionally be used to determine if a different indication does or does not create a different intended use.	X		If **YES** = Go to 3 If **NO** = Stop **AINE** or **NENI**
3. Do the devices have the same technological characteristics? • Note that this question should be interpreted narrowly. • Unless the subject device is practically identical to a predicate, answer 'no' to this question.		X	If **YES** = Stop **SESE** If **NO** = Go to 4
4. Do the different technological characteristics raise different S&E questions?		X	If **YES** = Stop **AINE or NENQ** If **NO** = Go to 5a
5a. Are methods available to evaluate the different technological characteristics?	X		If **YES** = continue If **NO** = Stop **NSE**
Are all necessary performance data available for review?		X	If **YES** = Go to If **NO** = Stop **AINN**
5b. Do the data demonstrate substantial equivalence?			If **YES** = Stop **SESE** If **NO** = Stop **NENL**

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XXI. Contact History

- June 18, 2014: K141619 assigned to Peter Yang
- July 1, 2014: RTA refusal email automatically sent
- July 25, 2014: K141619/S001 assigned to Peter Yang
- August 6, 2014: RTA acceptance email automatically sent
- September 19, 2014: AINN letter issued
- October 2, 2014: Sponsor inquired regarding using a standard not used by the FDA but with scientific justification. Peter Yang communicated that using such a standard would be appropriate given appropriate scientific justification and given a justification of what deviations and changes were made to the standard protocol.
- January 5, 2015: Sponsor inquired for clarity on deficiencies describing a protocol as "confusing."
- January 6, 2015: Peter Yang responded with examples.
- January 14, 2015: Supplement 002 received

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter Yang -S 2015.01.30 16:53:47 -05'00'
Branch Chief Sign-Off	Jiyoung Dang -S 2015.02.01 22:09:21 -05'00'
Division Sign-Off	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Premarket Notification [510(k)] Review

Traditional

K141619/S003

Date: April 2, 2015
To: The Record
From: Peter J. Yang, Ph.D.
Branch: Plastic and Reconstructive Surgery Branch II
Division: Division of Surgical Devices
Office: Office of Device Evaluation

Device Name: Luofucon Silver Foam Dressing
510(k) Holder: Huizhou Foryou Medical Devices Co., Ltd.
Address: North Shangxia Road, Dongjiang Hi-tec Industry Park
Huizhou, Guangdong 516005 China
Establishment Registration Number: 3007735241
Contact: Charles Shen
Official Correspondent, c/o Manton Business and Technology Services
853 Dorchester Ln, Unit-B
New Milford, NJ 07646
Phone: 608-217-9358
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TABLE OF CONTENTS

TABLE OF CONTENTS 1
I. Purpose of Submission, Document Summary History 2
II. Recommendation 4
III. Administrative Requirements 4
IV. Device Description 4
Overview 5
Materials and Manufacturing 6
Product Release 7
V. Indications for Use 8
VI. Predicate Device Comparison 9
VII. Labeling 10
VIII. Sterilization and Re-Use 12

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IX.	**Shelf Life and Stability Testing**	**12**
X.	**Biocompatibility**	**13**
XI.	**Software**	**14**
XII.	**Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**	**15**
XIII.	**Performance Testing – Bench**	**15**
	Density	15
	Absorbency Test: Free Swell Absorption Capacity	15
	Loss on Drying	15
	pH	15
	Silver Content	16
	Antibacterial Activity	16
	Determination of Minimum Effective Concentration	17
	Silver Leachability	17
XIV.	**Performance Testing – Animal**	**17**
XV.	**Performance Testing – Clinical**	**18**
XVI.	**Deficiencies and Response (S2)**	**18**
XVII.	**Antibacterial Protocol Review (S2)**	**25**
XVIII.	**Deficiencies for Second Hold and Sponsor's Response (Supplement 003)**	**25**
XIX.	**Interactive Review**	**28**
XX.	**Substantial Equivalence Discussion**	**30**
XXI.	**Contact History**	**30**

I. Purpose of Submission, Document Summary History

The 510(k) holder, Huizhou Foryou Medical Devices, would like to introduce the Luofucon Silver Foam Dressing into interstate commerce. The device is a family of four devices based off an open cell hydrophilic polyurethane foam dressing encapsulated with silver particles as an antimicrobial barrier with various backings.

- The first model is the foam itself.
- The second model adds a polyurethane film as a backing which is the same area as the foam.
- The third model modifies the film to be larger in area than the foam, with a pressure sensitive adhesive to secure the dressing on the patient's skin.
- The fourth model replaces the film in the third model with a non-woven material as the backing material, maintaining the same larger size with the pressure sensitive adhesive.

The Luofucon Silver Foam Dressing is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure sores
- Donor sites
- Surgical incisions
- Surgical excisions
- Burns (1st and 2nd degree)"

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The predicate device is K110062, MediPlus-Foam AG Dressings. It is a family of polyurethane foam dressings with various polyurethane film backing layers. The silver component in the predicate device is a silver net, essentially a glass matrix with elemental silver embedded in the matrix. It is indicated for "exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: Ulcers (venous, arterial, diabetic); Pressure Sores; Donor Sites; Surgical Incisions; Surgical Excisions; Burns (1st and 2nd degree)." The indications for use for the subject device and the predicate device are identical.

K141619 (received June 17, 2014) was assigned on June 18, 2014. The RTA checklist was completed on July 1, 2014 with an RTA1 decision. Supplement 001 (dated July 20, 2014) was received on June 23, 2014. The RTA checklist was completed with an RTAA recommendation on August 5, 2014 with branch concurrence on August 6, 2014. Consults were requested on August 7th, 2014 from Karoll Cortez, medical officer in DAGRID/INCB, and received on September 18, 2014. An AI letter was issued for K141619/S001 on September 21, 2014.

A summary of the issues with Supplement 1:

- The Sponsor claims, mostly in the labeling, that the device can reduce the infection in the wound. This statement is a Class III claim and should be substantiated with clinical data; moreover, it may be a drug claim warranting review jurisdiction transfer to CDER.
- It is unclear how much silver is contained in the device relative to the predicate device. The Sponsor has not compared the amount of silver.
- For most performance testing, only one sample of one lot was tested. The lack of triplicate testing extends to the shelf life and stability studies as well. The Sponsor should perform testing on three lots of devices, with multiple samples within each lot tested.
- For most performance testing, only one sample was tested – the first variant of the device, namely, the foam dressing itself. Other variants of the dressing, including those with additional layers of PET film and/or non-woven fabric layers, were not tested. The Sponsor should justify the use of the foam as the representative sample.
- Complete test reports for the performance tests are not provided.
- Labeling implies that the device may be left on the wound for more than 7 days without a clinical risk analysis to justify this labeling statement.

The response from the Sponsor, Supplement 002, was received on January 14, 2015. A second consult was requested from Brandon Kitchel, PRSB2 microbiologist, and received on January 23, 2015. The consult identified new issues with the antibacterial testing that were not identified Supplement 001. **Review of Supplement 002 begins in Section XVI.** Please note the detailed connection with K140954/S002, a submission from the same Sponsor. To summarize the noted issues:

- The antibacterial testing protocol was originally misread to mean that bacteria contacted the dressing for 3 days. Instead, the dressing was conditioned with a small amount of cell culture medium for 3 days, followed by inoculation and incubation for 24 hours. Thus, all of the bacterial testing only tests for 24 hours of effectiveness.
- Bacteria are combined with hot agar for counting. However, the temperature of the agar is likely to kill much of the bacteria. The testing should be redone with cooled agar plates.
- Packaging integrity test reports were not provided, but the Sponsor stated they were.
- The Sponsor did not correct an issue with the labeling (describing biocompatibility testing on the labeling as if the biocompatibility testing was above and beyond what was needed for clearance).

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- Symbols in the labeling should be accompanied by explanatory text.

Due to additional issues, the file was placed on a second hold on February 2, 2015 with consent from 510(k) program staff.

The Sponsor sent a question on February 9, 2015. Due to the use of a second hold and a wish to avoid a Submission Issue Meeting, we worked interactively off the clock to clarify aspects of the testing protocol. Brandon Kitchel was again consulted and provided a consult on February 17, 2015.

The Sponsor responded with Supplement 003 on March 24, 2015 and a third consult was issued to Brandon Kitchel on March 24, 2015 and received on March 27, 2015. The remaining issues were resolved in the Sponsor's response and remaining issues concerning the 510(k) Summary and Indications for Use statement were handled interactively.

No issues remain.

II. Recommendation

Substantially equivalent

Regulation Number: 21 CFR §
Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO

III. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if Prescription or OTC)	x			prescription
Truthful and Accurate Statement	x			
510(k) Summary or 510(k) Statement	x			
ClinicalTrials.gov Form FDA-3874			x	
Standards Form	x			Form 3654

IV. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	
Are "cleaning" instructions included for the end user?			x

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Overview

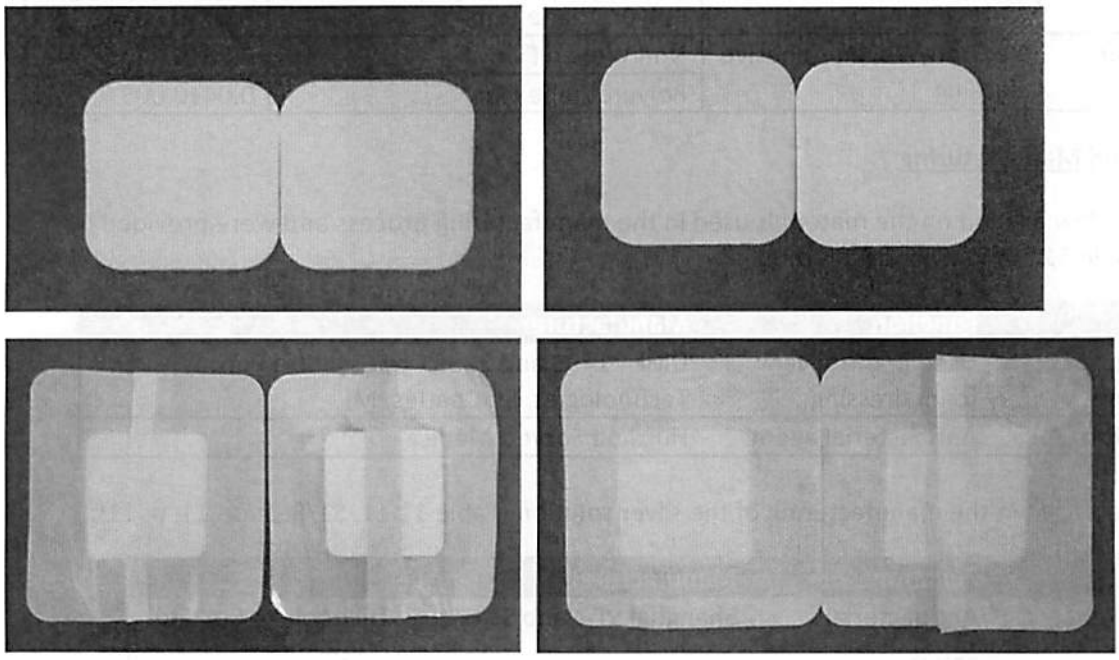
The device is a family of four devices that are all based on a "sterile, highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable polyurethane foam encapsulated with silver particles as an antimicrobial barrier" (S1/Section 11 p. 2).

The basic model is the foam itself.

The second variant described has an additional layer (25 ± 5 µm) of "non porous breathable polyurethane film (backing film)" laminated to the foam dressing. Both the film and the foam have the same surface area; this film is described as having a "cosmetic purpose."

The third variant described laminates a 40 ± 5 µm thick polyurethane film layer to the foam. Then a third layer of 40 ± 5 µm thick poly(ethylene terephthalate) (PET) film with a pressure sensitive adhesive is layered on top to provide a method for sticking the dressing on skin.

The fourth variant described is similar to the third variant. Instead of the third layer of PET film, a 280 ± 20 µm thick film of a "non-woven" material with a pressure sensitive adhesive is layered on top. This material is formed from "viscose rayon fiber and PET fiber." The non-woven material is claimed to be both "waterproof and semi permeable."



The adhesive used in the third and fourth variants is 2-ethyl hexyl acrylate, butyl acrylate, and acrylic acid dissolved in ethyl acetate and alcohol.

For the first and second variants, the sizes described are:

50 x 50 x 3 mm	50 x 50 x 5 mm
75 x 75 x 3 mm	75 x 75 x 5 mm
100 x 100 x 3 mm	100 x 100 x 5 mm
120 x 100 x 3 mm	120 x 100 x 5 mm
120 x 120 x 3 mm	120 x 120 x 5 mm

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150 x 100 x 3 mm	150 x 100 x 5 mm
150 x 150 x 3 mm	150 x 150 x 5 mm
200 x 100 x 3 mm	200 x 100 x 5 mm
200 x 150 x 3 mm	200 x 150 x 5 mm

For the third and fourth variants, the sizes described are:

Adhesive area: 50 x 50 mm	Foam: 20 x 20 x 3 mm
Adhesive area: 100 x 60 mm	Foam: 60 x 30 x 3 mm
Adhesive area: 100 x 100 mm	Foam: 50 x 50 x 3 mm
Adhesive area: 150 x 150 mm	Foam: 100 x 100 x 3 mm
Adhesive area: 180 x 180 mm	Foam: 110 x 110 x 3 mm

Foam: 20 x 20 x 5 mm
Foam: 60 x 30 x 5 mm
Foam: 50 x 50 x 5 mm
Foam: 100 x 100 x 5 mm
Foam: 110 x 110 x 5 mm

A summary table was provided by the Sponsor (S1/Section 11, p. 9, Table 11.5):

Variant	Description	Component	Thickness (mm)
First Variant	Basic Model	No Secondary Layer	N/A
Second Variant	Non-Adhesive Backing	Polyurethane Film	0.025±0.005
Third variant	PU/PET Adhesive Backing	Poly(ethylene terephthalate) Film	0.04±0.005
		Polyurethane Film	0.04±0.005
Fourth Variant	PU/Non-Woven Adhesive Backing	Non Woven Film	0.28±0.02
		Polyurethane Film	0.04±0.005

Materials and Manufacturing

(b)(4) Specifications

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(b)(4) Specifications

V. Indications for Use

The Sponsor provided this table in their Substantial Equivalence discussion (Section 12, p. 1). Only the indications are listed here (see Predicate Device Comparison section below for further discussion).

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-GomfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same

Reviewer comment: The indications are identical.

In addition to the Indications for Use, multiple claims are also presented throughout the submission, particularly in the Device Description and in the Labeling sections. For labeling claims, please see the Labeling section of this memo.

In Section 11, Device Description, the following claims are made about the device:

- 11.1, p. 2: "The dressing should be able to protect the wound from growth of a broad spectrum of bacterial or microorganisms."
- 11.1, p. 2: "Odour reduction results from the antibacterial effect in the dressing."

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Reviewer comment: The second claim is also present in the 510(k) Summary. Both claims are problematic. The first claim should be more strictly defined as acting as a barrier to infection. As stated, it implies that the dressing can potentially protect the wound from bacteria/microorganism growth within the wound itself, which is a claim based on the chemical action of the silver. Thus, CDER could have review jurisdiction. The second claim is not substantiated by any testing, and it is unclear what the mechanism of action is for the odor reduction itself.

Deficiency: Sponsor should remove statements regarding the implication of reduction of infection within the wound. Sponsor should provide a mechanism of action for the claim regarding "odour reduction" and substantiate this claim with performance testing. Alternatively, they may remove this statement from their labeling.

VI. Predicate Device Comparison

The Sponsor provided this table in their Substantial Equivalence section (Section 12, p. 1-2):

Description	Our Device	Predicate Device 1 (K110062)
Mechanism	Silver for antibacterial effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	Three days a
Single Use	Yes	Yes
Sterile	Sterile	Sterile

With regard to similarities, the Sponsor states (Section 12, p. 2) that both devices use silver and that both devices use polyurethane foam for "exudate absorption and wound management."

With regard to differences, the Sponsor states (Section 12, p. 2) that the predicate device uses a "multi-layered polyurethane structure," while the subject device uses either a single layered or double layered structure.

Reviewer comment: With regard to minor differences in the foam structure, this reviewer concurs.

The predicate device is K110062, MediPurpose MediPlus-Foam Ag Dressings. It is actually a family of devices submitted by MediPurpose Ltd. There are multiple forms of devices (drawing from the reviewer memo for K110062, authored by Sam Arepalli, PhD, PRSB2):

- MediPlus-Foam Ag: a "multi-layered, sterile highly absorbing open cell hydrophilic wound dressing composed of a thick, soft, smooth, elastic and breathable polyurethane (PU) foam sandwiched in between a breathable PU film and a silver net layer acting as an antimicrobial barrier."
- MediPlus-SuperFoam Ag: Thicker foam layer that is easier to bend
- MediPlus-ComfortFoam Ag: Foam dressing stuck to a breathable PU film coated in adhesive. Silver net layer remains on the bottom.

In S1 of the predicate K110062 submission, the Sponsor states that the silver net layer is composed of silver metal that has been immobilized or incorporated into a glass matrix ("Bactiglas"). The dressing is stated to contain 79 ppm of elemental silver.

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Reviewer comment: Both devices are made of polyurethane foam. The subject device is similar to the predicate devices in terms of having additional variants with a variety of backing films.

However, the devices are not comparable in how the silver is incorporated, and thus, how the silver is released. Although both devices use metallic silver, it is unclear how the silver in the predicate device is incorporated into the formulation. From the 510(k) Summary for K110062, there is no mention of the method by which silver is incorporated in the device, other than the statement that "the silver ions are incorporated in the dressing". In the subject device, the foam is polymerized and created in the presence of oligomer-encapsulated silver nanoparticles, whereas in the predicate device, the silver is part of a separate layer that presumably contacts the wound.

Also, while the predicate device contains 79 ppm of elemental silver, this does not provide sufficient information to compute the total silver in a given size of predicate dressing. Meanwhile, the subject device contains approximately 3 µg/cm3 silver, which for the highest size of dressing (200 x 150 x 5 mm = 150 cm3) = 450 µg silver. It is not clear how the silver content compares between the two dressings. For reference, the Luofucon Silver PU Antibacterial Foam Dressing (K140954, at the time of this writing on hold due to an AI letter) contains 45 mg silver for the same area of foam, 100 times the amount in the subject device.

Deficiency: The Sponsor does not address the differences in silver content. They should compare the total amount of silver and provide a justification for the change in the silver content of the subject device.

VII. Labeling

The Sponsor provided labeling in Section 13 of Supplement 001. Packaging for the immediate device, as well as box packaging and the package insert, was included.

General Labeling Checklist			
Label		**Instructions for Use**	
Company name & address	Yes	Company name, address, and contact info	Yes
System/component name	n/a	System name	n/a
Material	**No**	Device description	Yes
Part/lot number	Yes	Material	Yes
Single use statement	Yes	Indications for use	Yes
Sterile notation	Yes	Single use statement	Yes
Expiration date	Yes	Sterile notation	Yes
"See package insert" statement	**No**	Contraindications, warnings, precautions	Yes
Cautionary symbol restricting sale to a physician	Yes	Cautionary symbol restricting sale to a physician	Yes
Explanatory text to accompany symbols	Yes	Explanatory text to accompany symbols	n/a

Deficiency: Sponsor should add a statement to the immediate package labeling to see the package insert for complete Instructions for Use.

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Deficiency: Sponsor should include the materials of composition of the device on all labeling, including the components of the film.

Deficiency: Sponsor should make the following changes to their package labeling:
For each dressing size, please state the total maximum amount of silver in the dressing.
Please remove statements of "% reduction." Instead, you may include this suggested language: "This device has been shown to have 4 log bacterial reduction up to 7 days in vitro against the following bacteria: (mention the names of each strain tested)."
Please prominently display/state that silver is present as a preservative within the dressing.
Please include this statement in your 510(k) Summary and your labeling. You may wish to also add this statement to your Indications for Use.
You may wish to consider indicating how long the device should be used overall over multiple dressing changes.
Please add a statement to your labeling similar to the following: "Reduction in bacterial colonization or growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed."

Reviewer comment: The above deficiencies were also communicated to the Sponsor for their own K140954, Silver PU Antibacterial Foam Dressing, which at the time of this review is still on hold pending AI.

The Sponsor added several claims in their labeling, including:

- "It can... maintain moist environment to accelerate the healing process."
- "LUOFUCON Silver Foam Dressing can restrain the bacteria growing and reduce infection."
- "LUOFUCON Silver Foam Dressing has been tested in vitro and found to be effective against bacteria such as Staph..."
- "Dressing may be left in place for up to 7 days depending on patient's condition and the level of exudates."
- "The device is non-irritating, non-sensitising, non-cyctotoxic [sic] and biocompatible in a wound environment."
- The package labeling includes an "Adverse Reactions" section that details the biocompatibility testing performed on the device.

Deficiency: These additional labeling claims should be addressed.
The claim regarding "accelerating the healing process" implies that the dressing actively promotes wound healing and should be substantiated by clinical data in a PMA.
The claim regarding the reduction of infection is a drug claim (as the mechanism would presumably be through the release of silver ions) and so would lead to questions of product jurisdiction, i.e. whether CDER should review the device. The Sponsor should remove this statement and indicate that the silver is present to inhibit bacterial colonization within the dressing only.
The main issue with the description of bacteria is the term "such as." The Sponsor should only state those bacteria which their device has been shown to be effective against.
The labeling states that the dressing may be left on a patient for 7 days. This may lead a patient to assume that the silver lasts for 7 days, when the antibacterial effect only lasts for 3. The Sponsor should limit the amount of time that the device should remain on a patient to 3 days.

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The last two statements imply that the Sponsor has conducted initial testing above and beyond what is needed to demonstrate substantial equivalence for the purposes of FDA clearance. These statements should be removed.

In the "Warnings" section of the package insert, the Sponsor states that the device "is intended for short-term use up to 28 days." This length of time of leaving the device on a patient is not supported by their current submission.

Deficiency: The Sponsor should provide a justification for the length of time that this device should be used for. If multiple dressing changes are expected, the Sponsor should discuss the risk of repeated exposure to silver.

VIII. Sterilization and Re-Use

Sterility and shelf life information is provided in Section 14.

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam (moist heat), EO, Radiation):	EO	
b. Dose, for radiation (e.g., 25 – 50 kGy):	n/a	
c. Sterilant residuals remaining on the device:	0.27 mg EO; 2 mg/day max 6.75 mg ECH; 2 mg/day max	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	ISO 11135-1:2007 Validation: Half-cycle approach (Annex B)	
3. Sterility assurance level (SAL): (e.g., 10-6 for all devices (except 10-3 for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		No
If so, a description of the method: (e.g., LAL (Limulus Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	Immediate packaging: "enforced" paper – plastic pouch; heat sealed, 1 pc/pouch Intermediate packaging: Paper box Outer packaging: Corrugated board carton	

IX. Shelf Life and Stability Testing

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

X. Biocompatibility

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

XI. Software

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Not applicable to this device.

XII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable to this device.

XIII. Performance Testing – Bench

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

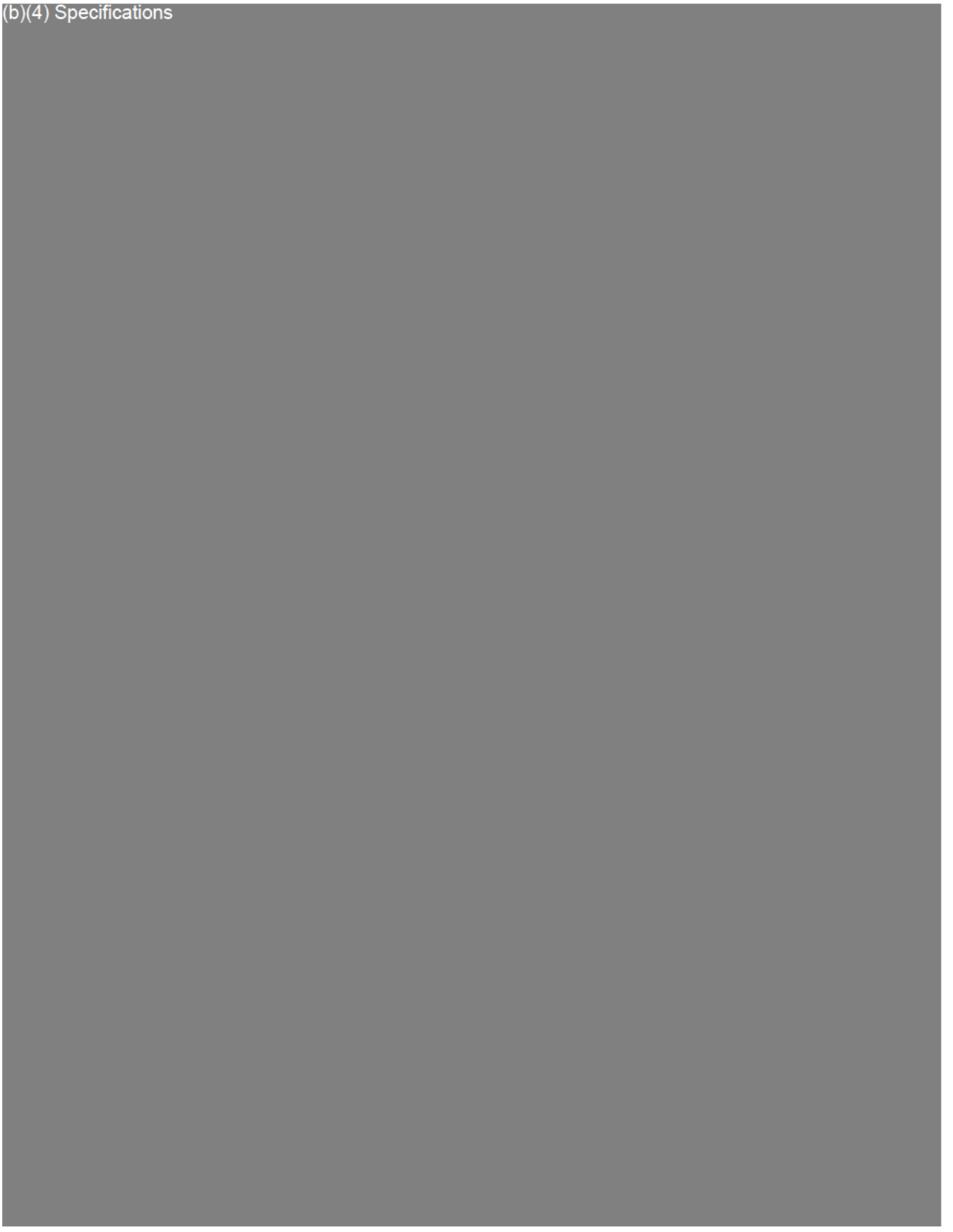
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(b)(4) Specifications



XIV. Performance Testing – Animal

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No animal data were provided.

XV. Performance Testing – Clinical

Not applicable to this device.

XVI. Deficiencies and Response (S2)

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

XVII. Antibacterial Protocol Review (S2)

(b)(4) Specifications

XVIII. Deficiencies for Second Hold and Sponsor's Response (Supplement 003)

(b)(4) Specifications

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Specifications

No issues remain.

XX. Substantial Equivalence Discussion

	YES	NO	
1. Is the predicate device legally marketed?	X		If YES = Go to 2 If NO = Stop NENO
2. Do the devices have the same intended use? • Review labeling to assure consistency w/ IFU form and 510(k) Summary. • Note that performance data can occasionally be used to determine if a different indication does or does not create a different intended use.	X		If YES = Go to 3 If NO = Stop AINE or NENI
3. Do the devices have the same technological characteristics? • Note that this question should be interpreted narrowly. • Unless the subject device is practically identical to a predicate, answer 'no' to this question.		X	If YES = Stop SESE If NO = Go to 4
4. Do the different technological characteristics raise different S&E questions?		X	If YES = Stop AINE or NENQ If NO = Go to 5a
5a. Are methods available to evaluate the different technological characteristics?	X		If YES = continue If NO = Stop NSE
Are all necessary performance data available for review?	X		If YES = Go to If NO = Stop AINN
5b. Do the data demonstrate substantial equivalence?	X		If YES = Stop SESE If NO = Stop NENL

XXI. Contact History

- June 18, 2014: K141619 assigned to Peter Yang
- July 1, 2014: RTA refusal email automatically sent
- July 25, 2014: K141619/S001 assigned to Peter Yang
- August 6, 2014: RTA acceptance email automatically sent
- September 19, 2014: AINN letter issued

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- October 2, 2014: Sponsor inquired regarding using a standard not used by the FDA but with scientific justification. Peter Yang communicated that using such a standard would be appropriate given appropriate scientific justification and given a justification of what deviations and changes were made to the standard protocol.
- January 5, 2015: Sponsor inquired for clarity on deficiencies describing a protocol as "confusing."
- January 6, 2015: Peter Yang responded with examples.
- January 14, 2015: Supplement 002 received
- February 2, 2015: Second hold issued to Sponsor
- February 9, 2015: Sponsor responded with questions regarding the use of the pour plate method vs. the spread plating method. Peter Yang responded that answers would be provided by early next week (around the 16th). Sponsor acknowledged.
- February 25, 2015: Peter Yang provided answers to Sponsor.
- March 10, 2015: Sponsor acknowledged and indicated they would follow FDA's advice. Sponsor asked if they could indicate that the device could be used for more than 3 days beyond the time of antibacterial preservative effectiveness.
- March 12, 2015: Peter Yang responded and indicated it was not appropriate because it lacked clinical justification; that is, a dressing with no more antibacterial preservative effectiveness would not be clinically justified to remain on a wound.
- March 24, 2015: Supplement 003 received
- March 31, 2015: Peter Yang contacted Sponsor with deficiencies regarding IFU, 510(k) Summary and labeling.
- April 1, 2015: Sponsor responded with updated documents. Peter Yang requested additional changes.
- April 2, 2015: Sponsor provided updated documents. Peter Yang acknowledged.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter Yang -S 2015.04.02 18:48:38 -04'00'
Branch Chief Sign-Off	Joseph Nielsen -S 2015.04.03 10:02:20 -04'00'
Division Sign-Off	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118