K161582

Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

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

06/03/2016

RE: Premarket Notification Traditional Section 510(k) Submission
Bain Medical Equipment (Guangzhou) Co., Ltd(***the Sponsor***)
DORA Tubing Sets for Hemodialysis(***the Device(s)***)

Dear Madam/Sir,

In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when the sponsor proposes to introduce its device(s) into interstate commerce for commercial distribution.

The CD-ROM provided with the submission is the eCopy of the submission; the eCopy is an exact duplicate of the paper copy.

If you have any question, please contact me vie email at info@mid-link.net or via fax at (240) 238-7587.

Thanks for your help.

Best Regards,

Fu, Lee 2016.06.05 22:47:11 +08'00'

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

Template Rev 1.0 03/26/2013

25

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Tel: +86-21-22815850
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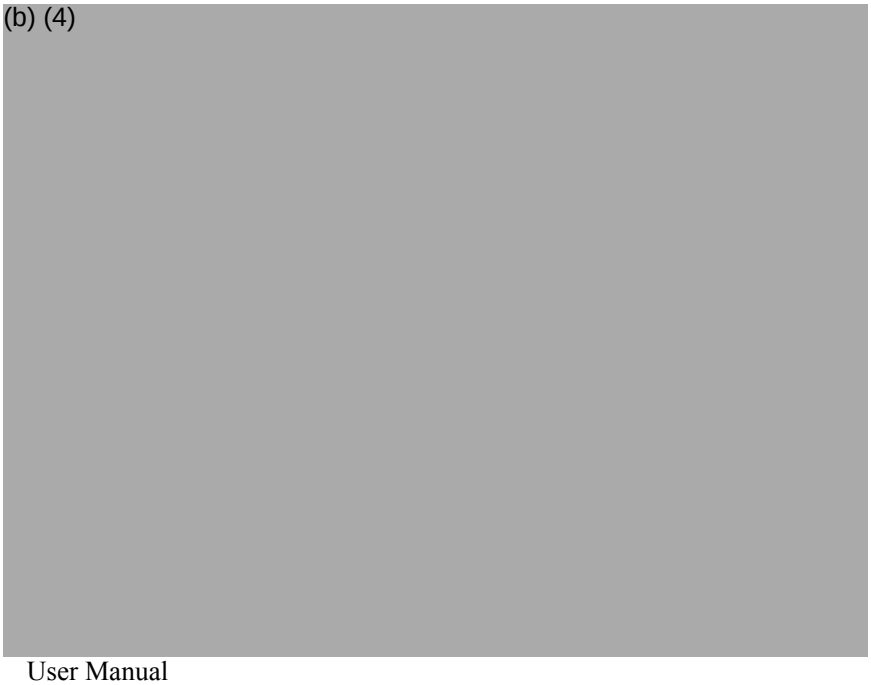
Enclosures

Table of Content

(b) (4)



User Manual
Seal Strength Test Report (Shelf Life)
ISO 8638 Test Report (Shelf Life)
ISO 594-2 Test Report (Shelf Life)
Repeated Closing Test Report (Shelf Life)
Cytotoxicity Test Report
Intracutaneous Reactivity Test Report
Sensitization Test Report
Acute Systemic Toxicity Report
Hemolysis Test (Indirect Contact)
Hemolysis Test (Direct Contact)
Partial Thromboplastin Time
Complement Activation Assay
in vitro Chromosomal Aberration Report
Bacterial Reverse Mutation Report
Mouse Bone Marrow Micronucleus Report
Pyrogen Report

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)	2. CONTACT NAME
Bain Medical Equipment (Guangzhou) Co., Ltd. No.10 Juncheng Road, Eastern Zone, Guangzhou Economic & Technolo Guangzhou Guangzhou CP 510760 US	Fangzhen Mu 2.1 E-MAIL ADDRESS ken@baingz.com 2.2 TELEPHONE NUMBER (include Area code) 20-82265249 340 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2767	

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

<u>Select an application type:</u>
[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

<u>3.2 Select one of the types below</u>
[X] Original Application

<u>Supplement Types:</u>
[ ] 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	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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)

25-May-2016

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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)*
06/03/2016	(b) (4)	

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)*		
Bain Medical Equipment (Guangzhou) Co., Ltd			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Di			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Guangzhou	Guangdong	510760	China
Contact Name			
Sophia Shao			
Contact Title	**Contact E-mail Address**		
Assistant Manager	sophia@baingz.com		

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

Company / Institution Name			
Mid-Link Consulting Co., Ltd			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+86-21-22815850		
Street Address	**FAX Number *(including area code)***		
P.O. Box 120-119	240-238-7087		
City	**State / Province**	**ZIP Code**	**Country**
Shanghai		200120	China
Contact Name			
Diana Hong			
Contact Title	**Contact E-mail Address**		
General Manager	info@mid-link.net		

PSC Publishing Services (301) 443-6740 EF

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):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FJK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 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	K072024	1	Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set	1	Nipro Medical Coporation
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Blood tubing sets

	Trade or Proprietary or Model Name for This Device		Model Number
1	DORA Tubing Sets for Hemodialysis	1	BAIN-BL-001E, BAIN-BL-002E,
2		2	BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E
3		3	
4		4	
5		5	

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

1 NONE	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	C.F.R. Section *(if applicable)*	Device Class
FJK	876.5820	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Gastroenterology/Urology		

Indications *(from labeling)*

The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.

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

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

Company / Institution Name: Bain Medical Equipment (Guangzhou) Co., Ltd

Establishment Registration Number

Division Name *(if applicable)*

Phone Number *(including area code)*

Street Address: No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological

FAX Number *(including area code)*

City	State / Province	ZIP Code	Country
Guangzhou	Guangdong	510760	China

Contact Name	Contact Title	Contact E-mail Address
Sophia Shao	Assistant Manager, RA	sophia@baingz.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

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

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H *(Continued)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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	

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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	

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	8638	ISO	Cardiovascular Implants and Extracorporeal Blood Circuit For Hemodialyzers, Hemodialfilters, and Hemofilters.	2010	
2	594-2	ISO	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings	1998	
3	10993-3	ISO	Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity, And Reproductive Toxicity	2003	
4	10993-5	ISO	Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity	2009	
5	10993-10	ISO	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	2010	
6	10993-11	ISO	Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity	2006	
7	F756	ASTM	Standard Practice For Assessment Of Hemolytic Properties Of Materials	2013	

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.

Additional Page of FDA Form 3654

Section I UTILIZATION OF STANDARDS

#	Standard No.	Standard Organization	Standard Title	Version	Date
8	F88	ASTM	Standard Test Method For Seal Strength Of Flexible Barrier Materials	2009	
9	11137-2	ISO	Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose.	2013	

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
Bain Medical Equipment (Guangzhou) Co., Ltd

2. Date of the Application/Submission Which This Certification Accompanies
05/09/2016

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District

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

City: Guangzhou
State/Province/Region: Guangdong
Country: China
ZIP or Postal Code: 510760

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): +86 20 8226 5249 ext.340
(Fax): +86 20 3206 7500

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)

Trade Name: DORA Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Model(s): BAIN-BL-001E, BAIN-BL-002E, BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E

Classification: 2
Product Code: FJK
Regulation Number: 876.5820

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

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
Mu Fangzhen	Management Representative

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Guangzhou
State/Province/Region	Guangdong
Country	China
ZIP or Postal Code	510760

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

(Tel): +86 20 8226 5249 ext.340

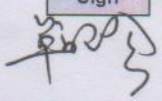
(Fax): +86 20 3206 7500

14. Date of Certification

05/09/2016

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

Sign



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:

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."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-207	
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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Referenced Documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Summary of practice	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Preparation of Test and Control Specimens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Hemoglobin Determination (Direct Method)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Collection and Preparation of Blood Substrates	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Procedure for the Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Precision and Bias	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Keywords	☒ 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

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

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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Referenced documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Interferences	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Sampling	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Aging and Conditioning	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Precision and Bias	☒ 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 10993-10：2010 Biological evaluation of medical devices-Part 10: Test for irritation and delayed-type hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-174	
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.	☐	☒
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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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[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: Test for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

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SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10：2010 Biological evaluation of medical devices-Part 10: Test for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General principles-Step-wise approach	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Pretest considerations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Skin sensitization tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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STANDARD TITLE
ISO 10993-10：2010 Biological evaluation of medical devices-Part 10: Test for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Key factors in interpretation of test results	☒ 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

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

ISO 10993-11:2006 Biological evaluation of medical devices-Part 11:Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-176	
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 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 systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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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 systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General considerations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Acute systemic toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity(subacute,subchronic and chronic sytemic	☒ 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

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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 10993-3:2003 Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-175	
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 10993-3:2003 Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-3:2003 Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Genotoxicity tests	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
5	Carcinogencity tests	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
6	Reproductive and developmental toxicity tests	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
7	Test report	☒ 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 10993-5:2009 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] # _____		
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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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?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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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 ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Cell lines	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Culture medium	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Preparation of cell stock culture	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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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?
8	Test procedures	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Test report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Assessment of results	☒ 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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#14-409	
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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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms, definitions, and abbreviated terms	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Definition and maintenance of product families for dose setting	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection and testing of product for establishing the sterilization dose	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Methods of dose establishment	☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Method 1: dose setting using bioburden information	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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STANDARD TITLE
ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Method 2: Dose setting using fraction positive information from incremental	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Method VDmax-Substantiation of 25kGy or 15kGy as the sterilization dose	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Sterilization dose audit	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Worked examples	☒ 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.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#6-129	
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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Dimensions and tolerances	☒ 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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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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PRAStaff@fda.hhs.gov

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Test methods	☒ 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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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 8638:2010 Cardiovascular implants and extracorporeal systems- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#9-89	
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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[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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 8638:2010 Cardiovascular implants and extracorporeal systems- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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STANDARD TITLE
ISO 8638:2010 Cardiovascular implants and extracorporeal systems- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Test methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Labelling	☒ 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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Tab #5 Cover Letter

1. Date of Submission: 05/02/2016

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District, 510760, Guangdong, P.R.China

Establishment Registration Number: Not yet registered or the Number

Contact Person: Shao, Sophia
Position: Assistant Manager, RA
Tel: +86 20 6685 6868 ext.218
Fax: +86 20 3206 7500
Email: sophia@baingz.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: DORA Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Model(s): BAIN-BL-001E, BAIN-BL-002E, BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E,

Regulatory Information
Classification Name: Set, Tubing, Blood, With and Without Anti-Regurgitation Valve
Classification: 2
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Intended Use Statement:

The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.

Table 1 Design and Use of the Proposed Device

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

5. Submission Type

Traditional;

6. Basis of the submission

New Device;

7. Prior Related Submission

There is no prior submission for the proposed device(s).

8. eCopy Statement

The CD-ROM provided with this submission is the eCopy of the submission; the eCopy is an exact duplicate of the paper copy.

Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 06/03/2016

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District, 510760, Guangdong, P.R.China

Establishment Registration Number: Not yet registered or the Number

Contact Person: Mu Fangzhen
Position: Management Representative
Tel: +86 20 8226 5249 ext.340
Fax: +86 20 3206 7500
Email: mufangzhen@baingz.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: DORA Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Model(s): BAIN-BL-001E, BAIN-BL-002E, BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E

Regulatory Information

Classification Name: Set, Tubing, Blood, With And Without Anti-Regurgitation Valve
Classification: 2
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Intended Use Statement:
The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.

Device Description

The proposed devices, DORA Tubing Sets for Hemodialysis, mainly consists of two tubes, which are arterial line with certain components in red and venous line with certain components in blue, as well as two accessories which are recirculate connector and drain bag.

They are available in five (5) models, following very similar design principles, and has some differences in dimensions and configurations.

The proposed devices are provided in sterile condition, it is subject to e-beam sterilization prior to release to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Identification of Predicate Device(s)

K072024
Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set;
Nipro Medical Coporation

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 8638 Third Edition 2010-07-01, Cadiovascular Implants And Extracorporeal Blood Circuit For Hemodialyzers, Hemodialfilters, And Hemofilters. 9-89
- ISO 594-2 Second Edition 1998-09-01, Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings. 6-129
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- ASTM F 756-08, Standard practice for assessment of hemolytic properties of material；
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device, K072024
Device Class	II	II
Product Code	FJK	FJK
Reg. Number	21 CFR part 876.5820	21 CFR part 876.5820
Intended Use	The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment.	Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis.
	The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.	The compatibility of available configuration is the responsibility of the physician in charge.
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device

Configuration	Arteria Line Venous Line	Tubing
	Drip Chamber	Drip Chamber;
	Branch Lines;	Infusion Tubing; Pressure Monitoring Lines;
	Female Luer Lock	Ports;
	Clamps	Clamps;
	Filter	Filters
	Drain Bag Recirculating Connector	N.A.
Performance	Conforms to ISO 8638:2010 ISO 594-2: 1998	Conforms to ISO 8638:2010 ISO 594-2: 1998
Materials	Various materials	Unknown
Biocompatibility	Cytotoxicity; Sensitization Intracutaneous reactivity; Acute systemic toxicity; Hemolysis Partial Thromboplastin Time Complement System In vitro Chromosomal Aberration Bacterial Reverse Mutation Mouse Bone Marrow Micronucleus Pyrogen	Conforms to ISO 10993-1
Sterilization	SAL (10^{-6})	SAL (10^{-6})

Discussion: The intended use of the proposed and predicate device are different in text and the compatible system, however, the compatible system claimed was supported by testing. The proposed device has two (2) additional accessories which are drain bag and the recirculating. These two (2) accessories will not affect the actual hemodialysis; the materials of the propose device have been evaluated for their biocompatibility. Therefore, no difference will result in any safety and effectiveness issue.

Conclusion:
Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.

Tab #8 Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Management Representative of Bain Medical Equipment (Guangzhou) Co., Ltd. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Authorized Signature
Mu Fangzhen
Management Representative
Bain Medical Equipment (Guangzhou) Co., Ltd.
05/09/2016

Tab #9 Device Descriptions

1. General Description

The proposed devices, Tubing Sets for Hemodialysis, are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. (b) (4)

The devices mainly consists of two tubes, which are arterial line with certain components in red and venous line with certain components in blue, as well as two accessories which are recirculate connector and drain bag. The mechanism of action is provided in *Section 3* and Principle of Operation in *Section 4*.

They are available in five (5) models, following very similar design principles, and has some differences in dimensions and configurations. The illustration for each model is provided in *Section 2*. Detail specifications of each model are provided in *Section 6*.

Design Drawings, including the assembly drawing and component drawings are provided in Tab #16 Assembly Drawing and Tab #17 Components Drawing. In these drawings, detail dimensions with tolerance are provided.

The proposed devices are intended to be used with a FDA cleared hemodialysis delivery system cleared under K121421. The conditions of use is provided in Section 5.

The proposed devices are provided in sterile condition, it is subject to e-beam sterilization prior to release to achieve a Sterility Assurance Level (SAL) of 10^{-6}. (b) (4) . Detail information is provided in Tab #12 Sterilization and Shelf Life.

The proposed devices are made of various raw materials, detail list of patient-contact materials, including colorants and additives, as well as the discussion of biocompatibility are provided in Tab #13 Biocompatibility.

The proposed devices are available in different level packages, in order to maintain sterility and prevent from damage during the transportation and storage. Detail information is provided in *Section 7*.

(b)(4) Device Illustrations

(b)(4) Device Illustrations

(b)(4) Device Illustrations

(b)(4) Device Illustrations

(b)(4) Device Illustrations

(b)(4) Device Illustrations

(b)(4) Device Illustrations

3. Mechanism of Action

The proposed device, Tubing Sets for Hemodialysis, is used as the extracorporeal blood circuit during hemodialysis treatment, by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump line interfaces with a pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit.

4. Principle of Operation

The Tubing Sets for Hemodialysis consists of an arterial line with some components in red, a venous line with some components in blue and other accessories.

The Arterial Line consists of the following main components:

(1)	Dialyser Connector	It is a standard female luer lock connector, which is used to connect with the arterial end of hemodialyzer. This component is in red for identification of the Arterial Line.
(2)	Cap for Dialyser Connector	It is used to prevent from entry of foreign matter.
(3)	Blood Injection Site	It is used for blood sample collection, which include a silicon plug. Blood sample is drawn by a needle which penetrates the silicon plug. This component is in red for identification of the Arterial Line.
(4)	On-off clamp	It is used on the main line and branch line. User can control the opening and closing the line by this clamp. This component is in red for identification of the Arterial Line.
(5)	Pump line	The pump line interfaces with a pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit.
(6)	Pump T Connector	It is a T connector for main line, pump line and heparin line.
(7)	Heparin line	It is the path for heparin injection.
(8)	Female Luer Lock (FLL)	It is standard female luer lock connector, which is connected to device with male Luer connector, such as syringe.
(9)	Cap for FLL	It is the cover for Female Luer Lock. It is used for sealing and to prevent entry of foreign matter.

(10)	Patient connector	It is standard male luer lock connector, which is connected to device with female Luer connector, such as AV Fistula Needles. This component is in red for identification of the Arterial Line.
(11)	Drip chamber	It is intended to eliminate the bubbles in blood. When blood enter drip chamber from lines, it may include a few bubbles. The chamber can allow the blood sit for a period to eliminate the bubble.
(12)	Transducer protector	It includes a hydrophobic membrane, designed to prevent from blood contamination of the pressure transducers of a hemodialysis delivery system.
(13)	Main line	It is used for blood delivery.
(14)	Branch line	It is used for injection of drug or nutrient solution.
(15)	Suspended Spike	It is used for priming.

The Venous Line consists of the following main components:

(1)	Dialyser Connector	It is a standard female luer lock connector, which is used to connect with the venous end of hemodialyzer. This component is in blue for identification of the Venous Line.
(2)	Cap for Dialyser Connector	It is used to prevent from entry of foreign matter.
(3)	Blood Injection Site	It is used for blood sample collection, which include a silicon plug. Blood sample is drawn by a needle which penetrates the silicon plug. This component is in blue for identification of the Venous Line.
(4)	On-off clamp	It is used on the main line and branch line. User can control the opening and closing the line by this clamp. This component is in blue for identification of the Venous Line.
(5)	Female Luer Lock (FLL)	It is standard female luer lock connector, which is connected to device with male Luer connector, such as syringe.
(6)	Cap for FLL	It is the cover for Female Luer Lock. It is used for sealing and to prevent entry of foreign matter.

(7)	Patient connector	It is standard male luer lock connector, which is connected to device with female Luer connector, such as AV Fistula Needles. This component is in blue for identification of the Venous Line.
(8)	Drip chamber	It is intended to eliminate the bubbles in blood. When blood enter drip chamber from lines, it may include a few bubbles. The chamber can allow the blood sit for a period to eliminate the bubble. In addition, there is a filter inside the chamber to prevent from thrombosis back to the patient.
(9)	Transducer protector	It includes a hydrophobic membrane, designed to prevent from blood contamination of the pressure transducers of a hemodialysis delivery system.
(10)	Main line	It is used for blood delivery.
(11)	Branch line	It is used for injection of drug or nutrient solution.

The accessories include:

(1)	Recirculating Connector	It is an optional component, which is used for connection of arterial line and venous line during priming, in order to reduce the amount of normal saline for priming.
(2)	Drain bag	It is used for collection of waste.

5. Conditions of Use

(b) (4)

6. Specifications

(b) (4)

7. Packaging Description

(b) (4)

Figure 7 Design Drawing of Immediate Package

(b) (4)

7.2 Transportation Package

(b) (4)

Tab #10 Proposed Labeling

1. General Description

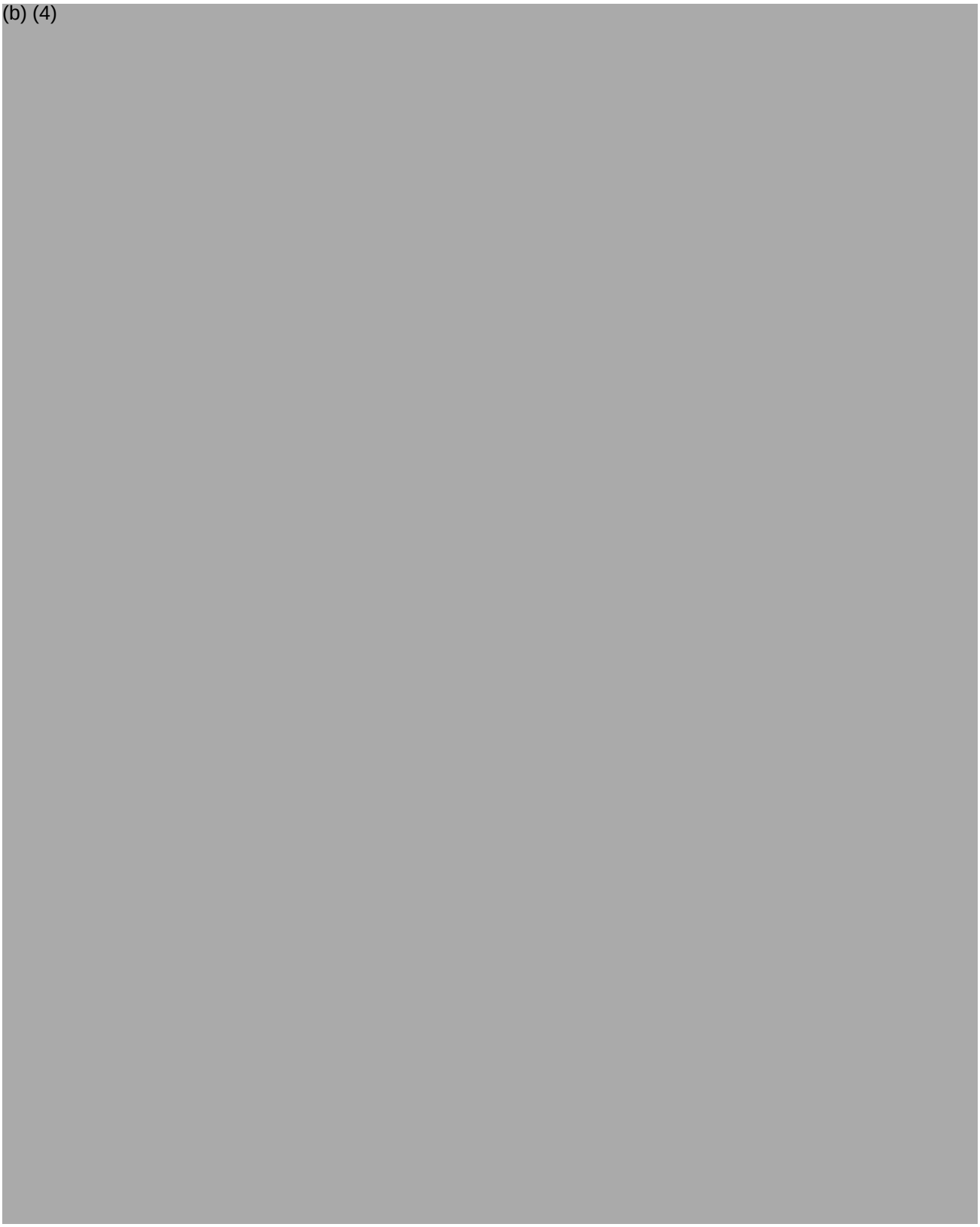
The proposed labeling of the proposed device contains:

a. Immediate Package Label;
b. Transportation Package Label;
c. User Manual.

The above identified proposed labeling complies with Title 21, CFR Section 801 labeling and the FDA Guidance, Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions, dated on April 23, 2008.

2. Immediate Package Label

(b) (4)



(b) (4)

3. Transport Package Label

(b) (4)

Figure 4 Transport Package Label – Side 2

4. User Manual

The user manual is provided in ***Tab #46 User Manual*** for review.

Tab #11 Substantially Equivalent Discussion

1. Identification of Predicate Device(s)

K072024
Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set;
Nipro Medical Coporation

2. SE Discussion

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device, K072024	Remark
Device Class	II	II	SE
Product Code	FJK	FJK	SE
Reg. Number	21 CFR part 876.5820	21 CFR part 876.5820	SE
Intended Use	The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment.	Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis.	Discussion 1
	(b) (4) [redacted] .	The compatibility of available configuration is the responsibility of the physician in charge.	Discussion 2
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	SE
Configuration	Arteria Line Venous Line	Tubing	Discussion 3
	Drip Chamber	Drip Chamber;	
	Branch Lines;	Infusion Tubing; Pressure Monitoring Lines;	
	Female Luer Lock	Ports;	
	Clamps	Clamps;	
	Filter	Filters	
	Drain Bag Recirculating Connector	N.A.	

Performance	Conforms to ISO 8638:2010 ISO 594-2: 1998	Conforms to ISO 8638:2010 ISO 594-2: 1998	SE
Materials	Various materials Detail in Tab #13	Unknown	Discussion 4
Biocompatibility	Cytotoxicity; Sensitization Intracutaneous reactivity; Acute systemic toxicity; Hemolysis Partial Thromboplastin Time Complement System In vitro Chromosomal Aberration Bacterial Reverse Mutation Mouse Bone Marrow Micronucleus Pyrogen	Conforms to ISO 10993-1	Discussion 4
Sterilization	SAL (10^{-6})	SAL (10^{-6})	SE
Labeling	Direction for Use	Direction for Use	SE
	Intended Use	Intended Use	SE
	Description	Description	SE
	Warnings and Cautions	Warnings and Cautions	SE

Discussion 1 – Intended Use (General)

The intended use of the proposed and predicate device are different in text, however, both of them are used to connect with a hemodialysis system and provide extracorporeal access to the patient's blood during hemodialysis. This difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 2 – Intended Use (Compatible System)

(b) (4) ; the compatible system of the predicate device is pending the physician in charge (multiple compatible system claimed). The instructions of the proposed device has clearly stated the compatible system, which will not result in any misuse. Bench testing included in this submission support the compatibility between the proposed device and the compatible system. This difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 3 – Configuration

Most configurations of proposed and predicate devices are the same except for their names. However, the proposed device has two (2) additional accessories which are drain bag and the recirculating. These two (2) accessories will not affect the actual hemodialysis, thus, this difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 4 – Materials and Biocompatibility

The materials of the predicate device are proprietary information; However, the proposed device (in final sterilized status) have been evaluated for various biocompatibility tests. The result demonstrated that no adverse reactions caused by the proposed devices. This difference will not result in any safety and effectiveness issue of the proposed device.

3. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

Tab #12 Sterilization and Shelf Life

1. Sterilization

1.1 General Description

The proposed device is provided sterile. It will subject to a radiation sterilization process, in its final package, to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

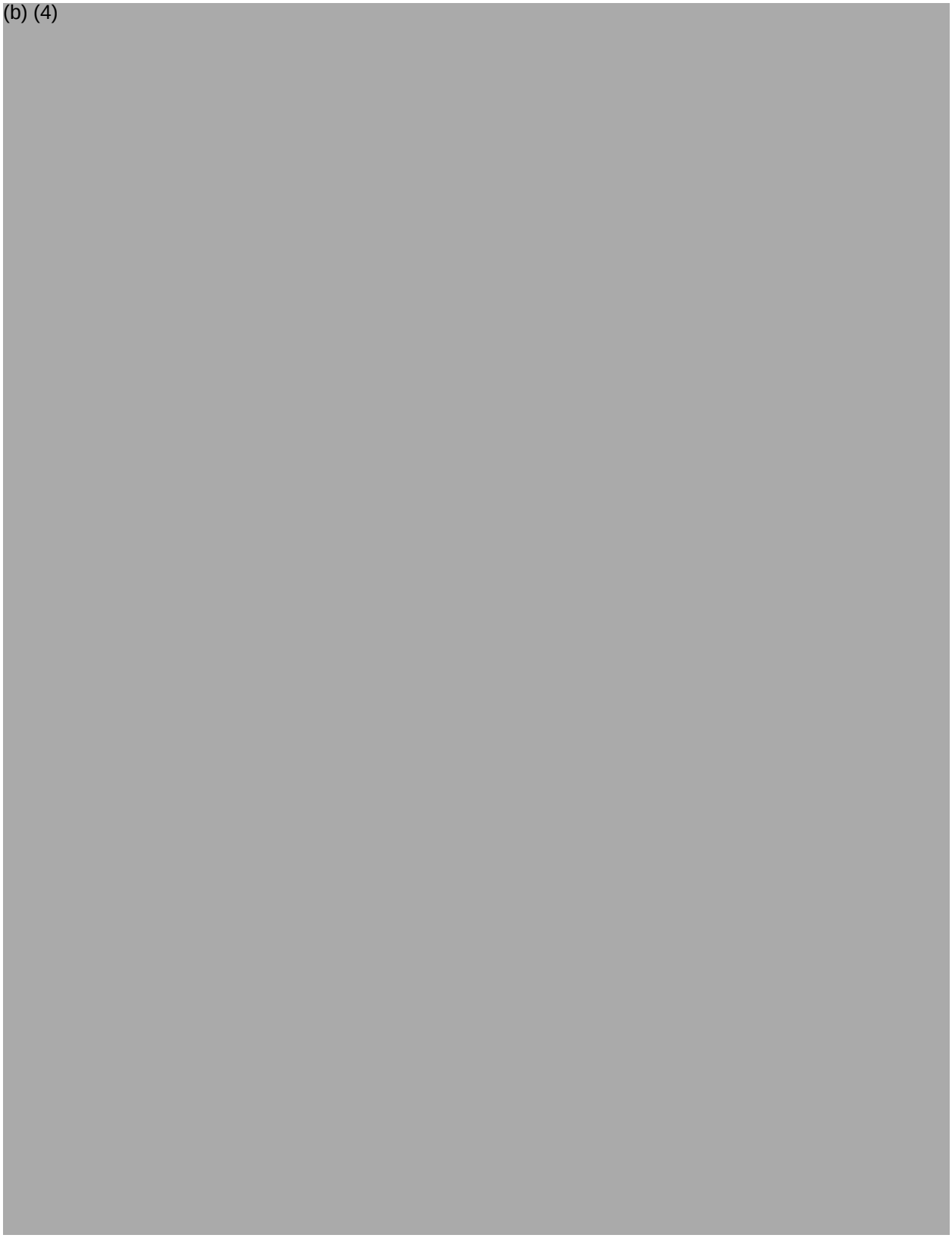
(b) (4) which was established per Method 1 Dosing Setting using Bioburden Information as qualified in *Section 7 of ISO 11137-2 Third Edition 2013-06-01, Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose*.

1.2 Endotoxin Limit

Medical device endotoxin contamination is associated with a risk of pyrogenic reactions in patients. Endotoxin limit is established as 20 USP Endotoxin Unit (EU) for the proposed device. Test for the five models of proposed device has been conducted by Limulus Amebocyte Lysate (LAL) method according to USP 38 <85> Bacterial Endotoxins Test. A copy of each report is provided in ***Tab #21 Bacterial Endotoxins Test Report***.

2. Shelf Life

(b) (4)



2.2 Verification using Real-Time Aging

(b) (4)

(b) (4)

Tab #12 Biocompatibility

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Tab #14 Software

This section is not applicable to the proposed device, because there is no software contained in the device.

Tab #15 Testing

1. Electrical Safety and EMC

   The proposed device does not require Electrical Safety and EMC tests, because it is not an active device.

2. Performance Testing – Bench

   The proposed devices were tested per the following standards, to evaluate its performance. The test results demonstrated that the proposed device comply with the standards requirements:

   - ISO 8638 Third Edition 2010-07-01, Cardiovascular Implants and Extracorporeal Blood Circuit For Hemodialyzers, Hemodialfilters, and Hemofilters.
   - ISO 594-2 Second Edition 1998-09-01, Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings.
   - ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;

   Copies of above tests reports are provided in:
   Tab #18 Tubing Sets Performance Test Report
   Tab #19 Luer Lock Test Report
   Tab #22 Seal Strength Test Report

   The flow rate of the proposed device after repeated clamping was tested on all of the five models. The test results complied with the design specifications. A copy the test report is provide in ***Tab #20 Repeated Clamping Test***.

3. Performance Testing – Animal

   No animal study is included in this submission.

4. Performance Testing – Clinical

   No clinical study is included in this submission.

Tab #16 Assembly Drawings

(b)(4) Assembly Drawings

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Tab #17 Components Drawings

(b)(4) Test Reports

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DORA®

Tubing Sets for Hemodialysis

Instructions for Use

Manufacturer has been granted certificate of ISO 13485

⚠ **Caution:** *Federal law restricts this device to sale by or on the order of a physician. Please read the instructions and warnings carefully before using this product.*

1. Indications for Use

The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.

2. Contraindications and Adverse Reactions

There are no known contraindications or adverse reactions to the use of the DORA Tubing Sets for Hemodialysis.

3. Material

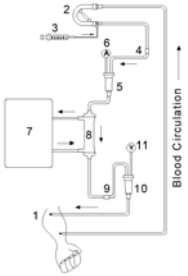
The major components of The DORA Tubing Sets for Hemodialysis are made from medical-grade PVC, PP, PC, ABS, fire-retardant PE and other medical-grade macromolecule materials. These products are fully sterilized by E-Beam radiation, sterile and non-pyrogenic, and contain no latex or DEHP. The tubing sets consist of a red Arterial Line and a blue Venous Line, and are soft, transparent, smooth and non-kink, which ensure the good liquidity. The filter in the venous air-capture chamber can prevent the blood clot going into patient's vein.

4. Storage Conditions

Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store these products in 0℃～40℃, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gas. **DO NOT** store it in warehouse with chemicals or moist articles.

5. Direction for Use

1) Pick out the tubing sets from the pouch. The Arterial and Venous connectors should be connected correctly with the dialyzer's Arterial and Venous Ports respectively.
2) Prime the tubing sets with Normal Saline, removing all air from tubing sets and hemodialyzer.
3) Before the 2) step finished, utilize heparin saline to prime the tubing and the dialyzer, which ensures the tubing is full of heparin saline, then stop pumping, and clamp all branch tubings.
4) Recheck and make sure all connectors are tight.
5) Start treatment referring to the dialyzer Instruction for Use.
6) The typical bloodline circuit diagram



1. Patient
2. Blood Pump
3. Heparinization
4. Access Port of the Arterial Line
5. Air-Capture Chamber of the Arterial Line
6. Transducer Protector (Arterial Pressure)
7. Dialysate
8. Hemodialyser
9. Access Port of the Venous Line
10. Air-Capture Chamber of the Venous Line
11. Transducer Protector (Venous Pressure)

6. Precautions in Use

1) This product should be used under medical supervision. Use aseptic technique throughout connection, priming and treatment. The validity period is three years after the sterilization day. Please check the expiration date prior to use, to prevent contamination, **DO NOT** use any expired product.
2) **DO NOT** use a sharp tool when opening the carton or an individual package. **DO NOT** use the tubing sets if the package is damaged.
3) Open the pouch and pick out the tubing sets carefully. Check that all connections are secure and protective caps are in place. The tubing sets must be used as soon as the packaging and the protective caps have been removed.
4) The safety of the connection to dialyzers should be guaranteed. **DO NOT** use the tubing sets if the hemodialyzer connector can not fit for the hemodialyzer. Check from time to time to ensure that all of the connectors are tight to prevent blood leakage or the air bubbles and avoid air embolism. Make sure the tubing set is properly installed to the hemodialysis machine to prevent kinks during treatment as they may create a hazardous reduction in the cross section of the tubing with a harmful effect on blood components and a risk of hemolysis.
5) If the tubing set can not be properly connected, or there is any fluid leakage or presence of air bubbles, take corrective measures or replace with new tubing sets. Any abnormal condition should be properly treated under the direction of physician.
6) This product is for single use only and reuse is prohibited. Reprocessing of this product may lead to adverse patient reactions and/or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste so as to prevent infection.
7) The transducer protector (TP) of this product is welded by high frequency bonding technology. If it is wetted by saline or blood during hemodialysis, clamp the tubing which connects with the transducer protector, and then replace with another new transducer protector. Make sure that a transducer protector was installed on each pressure monitoring line prior to patient use.
8) **DO NOT** use any needle larger than 21 gauge to puncture the injection site.
9) General disinfectants in clinical settings are compatible with tubing set in external application.
10) To ensure the normal use of the air-capture chamber, its level marking should be 1 *cm* below the upper cover.

7. Symbol

	Do Not Reuse		Use by (Expiration) Date
LOT	Batch Code		Pump Segment Diameter
	Date of Manufacture	REF	Catalogue Number
	Caution		Manufacturer
	Temperature Limitation		Consult Instructions for Use
	Keep away from Sunlight		Keep Dry
	Do Not Use if Package is Damaged	STERILE R	Sterile Fluid Path by E-Beam Radiation
Σ	Sufficient for	%	Humidity Limitation
PHT DEHP	DEHP Free		Non-pyrogenic
	Handle with Care		This Way Up

8. Parameter

Model	Priming Volume (A±10%)	Positive Pressure (*mm*Hg)	Negative Pressure (*mm*Hg)	Blood Flow Rate Limitations	Dimensional Parameters (*mm*)
BAIN-BL-001E	A=182	500	-500	500 mL/min	Arterial Line Length: 3500 Venous Line Length: 3000 Pump Tube OD: 12
BAIN-BL-002E	A=163				
BAIN-BL-003E	A=177				
BAIN-BL-004E	A=163				
BAIN-BL-005E	A=187				

<Manufacturer>

Bain Medical Equipment (Guangzhou) Co., Ltd.
Add.: No.10 Juncheng Road, Eastern Area, Economic & Technological

Development District, Guangzhou, China, 510760
Tel: +86-20-8226 5249 Fax:+86-20-3206 7500
E-mail: sales@baingz.com

⚠ Keep this Instruction for Use after all of the products in this carton are used up.

Ver. 2016-06.02

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K161582/S001

MID-LINK
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Shanghai, 200237, China

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

9/26/2016

RE: K161582 RTA Response
Bain Medical Equipment (Guangzhou) Co., Ltd
DORA Tubing Sets for Hemodialysis

Dear Madam/Sir,

Enclosed please kindly find as the response submitted on behalf of for Bain Medical Equipment (Guangzhou) Co., Ltd (hereinafter as "the sponsor"), for its product to each of question in your RTA designation letter dated Jun 8, 2016.

The eCopy provided is an exact duplicate of the paper copy.

I wish the response could address all of your concerns. Please feel free to contact me if you have any further questions via email at info@mid-link.net or via fax at (240) 238-7587.

Best Regards,

Diana Hong.

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

44

Mid-Link Consulting Co., Ltd
P.O. Box 237-023
Shanghai, 200237, China

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

9/26/2016

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Best Regards,

Diana Hong

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

Table of Content

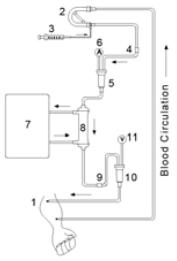
Tubing Sets for Hemodialysis

Instructions for Use

Manufacturer has been granted certificate of ISO 13485

⚠ **Caution:** *Federal law restricts this device to sale by or on the order of a physician. Please read the instructions and warnings carefully before using this product. Keep this Instructions for Use after all of the products in this carton are used up.*

1. **Indications for Use**
   The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect hemodialyzer with patient in hemodialysis treatment. The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.
2. **Intended Patient Population**
   The DORA Tubing Sets for Hemodialysis are only for adult patients.
3. **Contraindications and Adverse Reactions**
   There are no known contraindications or adverse reactions to the use of the DORA Tubing Sets for Hemodialysis.
4. **Material**
   The major components of The DORA Tubing Sets for Hemodialysis are made from medical-grade PVC, PP, PC, ABS, fire-retardant PE and other medical-grade macromolecule materials. These products are fully sterilized by E-Beam radiation, sterile and non-pyrogenic, and contain no latex or DEHP. The tubing sets consist of a red Arterial Line and a blue Venous Line, and are soft, transparent, smooth and non-kink, which ensure the good liquidity. The filter in the venous air-capture chamber can prevent the blood clot going into patient's vein.
5. **Storage Conditions**
   Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store these products in 0℃～40℃, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gas. **DO NOT** store it in warehouse with chemicals or moist articles.
6. **Direction for Use**
   1) Pick out the tubing sets from the pouch. The Arterial and Venous connectors should be connected correctly with the dialyzer's Arterial and Venous Ports respectively.
   2) Prime the tubing sets with Normal Saline, removing all air from tubing sets and hemodialyzer.
   3) Before the 2) step finished, utilize heparin saline to prime the tubing and the dialyzer, which ensures the tubing is full of heparin saline, then stop pumping, and clamp all branch tubings.
   4) Recheck and make sure all connectors are tight.
   5) Start treatment referring to the dialyzer Instruction for Use.
   6) The typical bloodline circuit diagram



1. Patient
2. Blood Pump
3. Heparinization
4. Access Port of the Arterial Line
5. Air-Capture Chamber of the Arterial Line
6. Transducer Protector (Arterial Pressure)
7. Dialysate
8. Hemodialyser
9. Access Port of the Venous Line
10. Air-Capture Chamber of the Venous Line
11. Transducer Protector (Venous Pressure)

7. **Precautions in Use**
   1) This product should be used under medical supervision. Use aseptic technique throughout connection, priming and treatment. The validity period is three years after the sterilization day. Please check the expiration date prior to use, to prevent contamination.
   2) Open the pouch and pick out the tubing sets carefully. Check that all connections are secure and protective caps are in place. The tubing sets must be used as soon as the packaging and the protective caps have been removed.
   3) If the tubing set can not be properly connected, or there is any fluid leakage or presence of air bubbles, take corrective measures or replace with new tubing sets. Any abnormal condition should be properly treated under the direction of physician.
   4) This product is for single use only and reuse is prohibited. Reprocessing of this product may lead to adverse patient reactions and/or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste so as to prevent infection.
   5) The transducer protector (TP) of this product is welded by high frequency bonding technology. If it is wetted by saline or blood during hemodialysis, clamp the tubing which connects with the transducer protector, and then replace with another new transducer protector. Make sure that a transducer protector was installed on each pressure monitoring line prior to patient use.
   6) General disinfectants in clinical settings are compatible with tubing set in external application.
   7) To ensure the normal use of the air-capture chamber, its level marking should be 1 *cm* below the upper cover.
8. **Warnings**
   1) **DO NOT** use any expired product.
   2) **DO NOT** use a sharp tool when opening the carton or an individual package. **DO NOT** use the tubing sets if the package is damaged.
   3) The safety of the connection to dialyzers should be guaranteed. **DO NOT** use the tubing sets if the hemodialyzer connector can not fit for the hemodialyzer. Check from time to time to ensure that all of the connectors are tight to prevent blood leakage or the air bubbles and avoid air embolism. Make sure the tubing set is properly installed to the hemodialysis machine to prevent kinks during treatment as they may create a hazardous reduction in the cross section of the tubing with a harmful effect on blood components and a risk of hemolysis.
   4) **DO NOT** use any needle larger than 21 gauge to puncture the injection site when sampling.
9. **Symbol**

	Do Not Reuse		Use by (Expiration) Date
LOT	Batch Code		Pump Segment Diameter
	Date of Manufacture	REF	Catalogue Number
	Caution		Manufacturer
	Temperature Limitation		Consult Instructions for Use
	Keep away from Sunlight		Keep Dry
	Do Not Use if Package is Damaged	STERILE R	Sterile Fluid Path by E-Beam Radiation
Σ	Sufficient for	%	Humidity Limitation
PHT DEHP	DEHP Free		Non-pyrogenic
	Handle with Care		This Way Up

10. **Parameter**

Model	Priming Volume (A±10%)	Positive Pressure (*mm*Hg)	Negative Pressure (*mm*Hg)	Blood Flow Rate Limitations	Dimensional Parameters (*mm*)
BAIN-BL-001E	A=182	500	-500	500 mL/min	Arterial Line Length: 3500 Venous Line Length: 3000 Pump Tube OD: 12
BAIN-BL-002E	A=163				
BAIN-BL-003E	A=177				
BAIN-BL-004E	A=163				
BAIN-BL-005E	A=187				

<Manufacturer>

Bain Medical Equipment (Guangzhou) Co., Ltd.
Add.: No.10 Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou, China, 510760
Tel: +86-20-8226 5249 Fax:+86-20-3206 7500
E-mail: sales@baingz.com

Reserved for Distributor Information in the future.

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Tab #16 Biocompatibility

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K161582/S002

Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

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

5/11/2017

RE: K161582 – Supplement 2
Bain Medical Equipment (Guangzhou) Co., Ltd
DORA Tubing Sets for Hemodialysis

Dear Madam/Sir,

Enclosed please kindly find as the response submitted on behalf of for Bain Medical Equipment (Guangzhou) Co., Ltd (hereinafter as "*the sponsor*"), for its product to each of question in your deficiency letter dated 11/24/2016.

The eCopy provided is an exact duplicate of the paper copy.

I wish the response could address all of your concerns. Please feel free to contact me if you have any further questions via at info@mid-link.net or fax at (240) 238-7587.

Best Regards,

Diana Hong

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

MID-LINK
www.mid-link.net info@mid-link.net

Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

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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Best Regards,

Diana Hong

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

Table of Content

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)*
K161582

Device Name
DORA Tubing Sets for Hemodialysis

Indications for Use *(Describe)*
The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge.

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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Tab #5 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 03/14/2017

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District, 510760, Guangdong, P.R.China

Establishment Registration Number: Not yet registered or the Number

Contact Person: Mu Fangzhen
Position: Management Representative
Tel: +86 20 8226 5249 ext.340
Fax: +86 20 3206 7500
Email: mufangzhen@baingz.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: DORA Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Model(s): BAIN-BL-001E, BAIN-BL-002E, BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E

Regulatory Information

Classification Name: Set, Tubing, Blood, With And Without Anti-Regurgitation Valve
Classification: 2
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Intended Use Statement:
The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge.

Device Description

The proposed devices, DORA Tubing Sets for Hemodialysis, mainly consists of two tubes, which are arterial line with certain components in red and venous line with certain components in blue, as well as two accessories which are recirculate connector and drainage bag.

They are available in five (5) models, following very similar design principles, and has some differences in dimensions and configurations.

The proposed devices are provided in sterile condition, it is subject to e-beam sterilization prior to release to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Identification of Predicate Device(s)

K072024
Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set
Nipro Medical Coporation

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 8638 Third Edition 2010-07-01, Cadiovascular Implants And Extracorporeal Blood

Circuit For Hemodialyzers, Hemodialfilters, And Hemofilters. 9-89

- ISO 594-2 Second Edition 1998-09-01, Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings. 6-129
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- ASTM F 756-08, Standard practice for assessment of hemolytic properties of material;
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device, K072024
Device Class	II	II
Product Code	FJK	FJK
Regulation Number	21 CFR part 876.5820	21 CFR part 876.5820
Intended Use	The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment.	Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis.
	The compatibility of available configurations is the responsibility of the physician/clinician in charge.	The compatibility of available configuration is the responsibility of the physician in charge.
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device
Configuration	Arteria Line Venous Line	Tubing

	Drip Chamber	Drip Chamber
	Branch Lines	Infusion Tubing; Pressure Monitoring Lines;
	Female Luer Lock	Ports
	Clamps	Clamps
	Filter	Filters
	Drain Bag Recirculating Connector	N.A.
Performance	Conforms to ISO 8638:2010 ISO 594-2: 1998	Conforms to ISO 8638:2010 ISO 594-2: 1998
Materials	Various materials	Unknown
Biocompatibility	Cytotoxicity; Sensitization Intracutaneous reactivity; Acute systemic toxicity; Hemolysis Partial Thromboplastin Time Complement System In vitro Chromosomal Aberration Bacterial Reverse Mutation Mouse Bone Marrow Micronucleus Pyrogen	Conforms to ISO 10993-1
Sterilization	SAL (10^{-6})	SAL (10^{-6})

Discussion: The intended use of the proposed and predicate device is different in text. The proposed device has two (2) additional accessories which are drain bag and the recirculating. These two (2) accessories will not affect the actual hemodialysis; the materials of the propose device have been evaluated for their biocompatibility. Therefore, no difference will result in any safety and effectiveness issue.

Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.

DORA®

Tubing Sets for Hemodialysis

Instructions for Use

Manufacturer has been granted certificate of ISO 13485

⚠ **Caution:** *Federal law restricts this device to sale by or on the order of a physician. Please read the instructions and warnings carefully before using this product. Keep this Instructions for Use after all of the products in this carton are used up.*

1. Indications for Use

The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician / clinician in charge.

2. Intended Patient Population

The DORA Tubing Sets for Hemodialysis are only for adult patients.

3. Contraindications and Adverse Reactions

There are no known contraindications or adverse reactions to the use of the DORA Tubing Sets for Hemodialysis.

4. Material

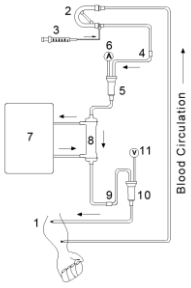
The major components of The DORA Tubing Sets for Hemodialysis are made from medical-grade PVC, PP, PC, ABS, fire-retardant PE and other medical-grade macromolecule materials. These products are fully sterilized by E-Beam radiation. It has a sterile, non-toxic and non-pyrogenic fluid path. The device is manufactured with components and materials that do not contain natural rubber latex components. The tubing sets consist of a red Arterial Line and a blue Venous Line, and are soft, transparent, smooth and non-kink, which ensure the good liquidity. The filter in the venous air-capture chamber (drip chamber) can prevent the blood clot going into patient's vein.

5. Storage Conditions

Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store these products in 0℃～40℃, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gas. **DO NOT** store it in warehouse with chemicals or moist articles.

6. Direction for Use

1) Pick out the tubing sets from the pouch. The Arterial and Venous connectors should be connected correctly with the dialyzer's Arterial and Venous Ports respectively.
2) Prime the tubing sets with Normal Saline, removing all air from tubing sets and hemodialyzer, then stop pumping, and clamp all branch tubings.
3) Recheck and make sure all connectors are tight.
4) Start treatment referring to the dialyzer Instruction for Use.
5) The typical bloodline circuit diagram



1. Patient
2. Blood Pump
3. Heparinization
4. Access Port of the Arterial Line
5. Arterial Air-Capture Chamber (Drip Chamber)
6. Transducer Protector (Arterial Pressure)
7. Dialysate
8. Hemodialyzer
9. Access Port of the Venous Line
10. Venous Air-Capture Chamber (Drip Chamber)
11. Transducer Protector (Venous Pressure)

7. Precautions in Use

1) This product should be used under medical supervision. Use aseptic technique throughout connection, priming and treatment. The validity period is three years after the sterilization day. Please check the expiration date prior to use, to prevent contamination.
2) Open the pouch and pick out the tubing sets carefully. Check that all connections are secure and protective caps are in place. The tubing sets must be used as soon as the packaging and the protective caps have been removed.
3) If the tubing set can not be properly connected, or there is any fluid leakage or presence of air bubbles, take corrective measures or replace with new tubing sets. Any abnormal condition should be properly treated under the direction of physician.
4) This product is for single use only and reuse is prohibited. Reprocessing of this product may lead to adverse patient reactions and / or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste so as to prevent infection.
5) The transducer protector (TP) of this product is welded by high frequency bonding technology. If it is wetted by saline or blood during hemodialysis, clamp the tubing which connects with the transducer protector, and then replace with another new transducer protector. Make sure that a transducer protector was installed on each pressure monitoring line prior to patient use.
6) To ensure the normal use of the air-capture chamber, air-capture chamber (drip chamber) fill level should be 1 *cm* below the level marking.

8. Warnings

1) **DO NOT** use any expired product.
2) **DO NOT** use a sharp tool when opening the carton or an individual package. **DO NOT** use the tubing sets if the package is damaged.
3) The safety of the connection to dialyzers should be guaranteed. **DO NOT** use the tubing sets if the hemodialyzer connector can not fit for the hemodialyzer.
4) Check from time to time to ensure that all of the connectors are tight to prevent blood leakage or the air bubbles and avoid air embolism.
5) Make sure the tubing set is properly installed to the hemodialysis machine to prevent kinks during treatment as they may create a hazardous reduction in the cross section of the tubing with a harmful effect on blood components and a risk of hemolysis.
6) Significant hemolysis of red blood cells can occur in kinked blood tubing, especially in the post-pump, arterial tubing segment.
7) **DO NOT** use any needle larger than 21 gauge to puncture the injection site when sampling.

9. Parameter

Model	Total Priming Volume (±10%)	Positive Pressure (*mm*Hg)	Negative Pressure (*mm*Hg)	Blood Flow Rate Limitations	Dimensional Parameters (*mm*)
BAIN-BL-001E	182	500	-500	500 mL/min	Arterial Line Length: 3500 Venous Line Length: 3000 Pump Tube OD: 12
BAIN-BL-002E	163				
BAIN-BL-003E	177				
BAIN-BL-004E	163				
BAIN-BL-005E	187				
The recommended maximum operating pressures for the transducer protector is 500 mmHg					
NOTE: The hemodialysis delivery system which is compatible with these products is Fresenius 2008K manufactured by Fresenius Medical Care North America.					

10. Symbol

	Do Not Reuse		Use by (Expiration) Date
LOT	Batch Code		Pump Segment Diameter
	Date of Manufacture	REF	Catalogue Number
	Caution		Manufacturer
	Temperature Limitation		Consult Instructions for Use
	Keep away from Sunlight		Keep Dry
	Do Not Use if Package is Damaged	STERILE R	Sterile Fluid Path by E-Beam Radiation
	Non-pyrogenic		Humidity Limitation
	Handle with Care		This Way Up

11. Components

Air-Capture Chamber (Drip Chamber): It is intended to capture air and which can provide compliance to the blood circuit or allow pressure to be monitored

Pump Segment: Portion of the extracorporeal blood circuit that is acted upon by the blood pump

Transducer Protector: Component of the extracorporeal blood circuit that is intended to provide an interconnection between the extracorporeal blood circuit and the haemodialysis machine while allowing the pressure within the extracorporeal blood circuit to be measured by the machine

Clamps: It is used on the main tubing and branch tubing, control open and close of bloodstream assess through its opening & closing.

Access Port (Injection Port): It is for blood sampling / injection before or after treatment. Needle head puncture through the silicone stopper to sample blood / give injection.

Priming Sets: When pre-flushing the extracorporeal blood circuit, puncture it into the saline bag or bottle.

Drain Bag: It is intended to collect the waste fluid.

Heparin Line: Assess to inject heparin, whose length is based on its position in the hemodialysis machine.

Arterial Tubing [Red] / Veinous Tubing [Blue]: It is the main component for channeling blood in hemodialysis treatment.

<Manufacturer>

Bain Medical Equipment (Guangzhou) Co., Ltd.
Add.: No.10 Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou, China, 510760
Tel: +86-20-8226 5249 **Fax:** +86-20-3206 7500
E-mail: sales@baingz.com

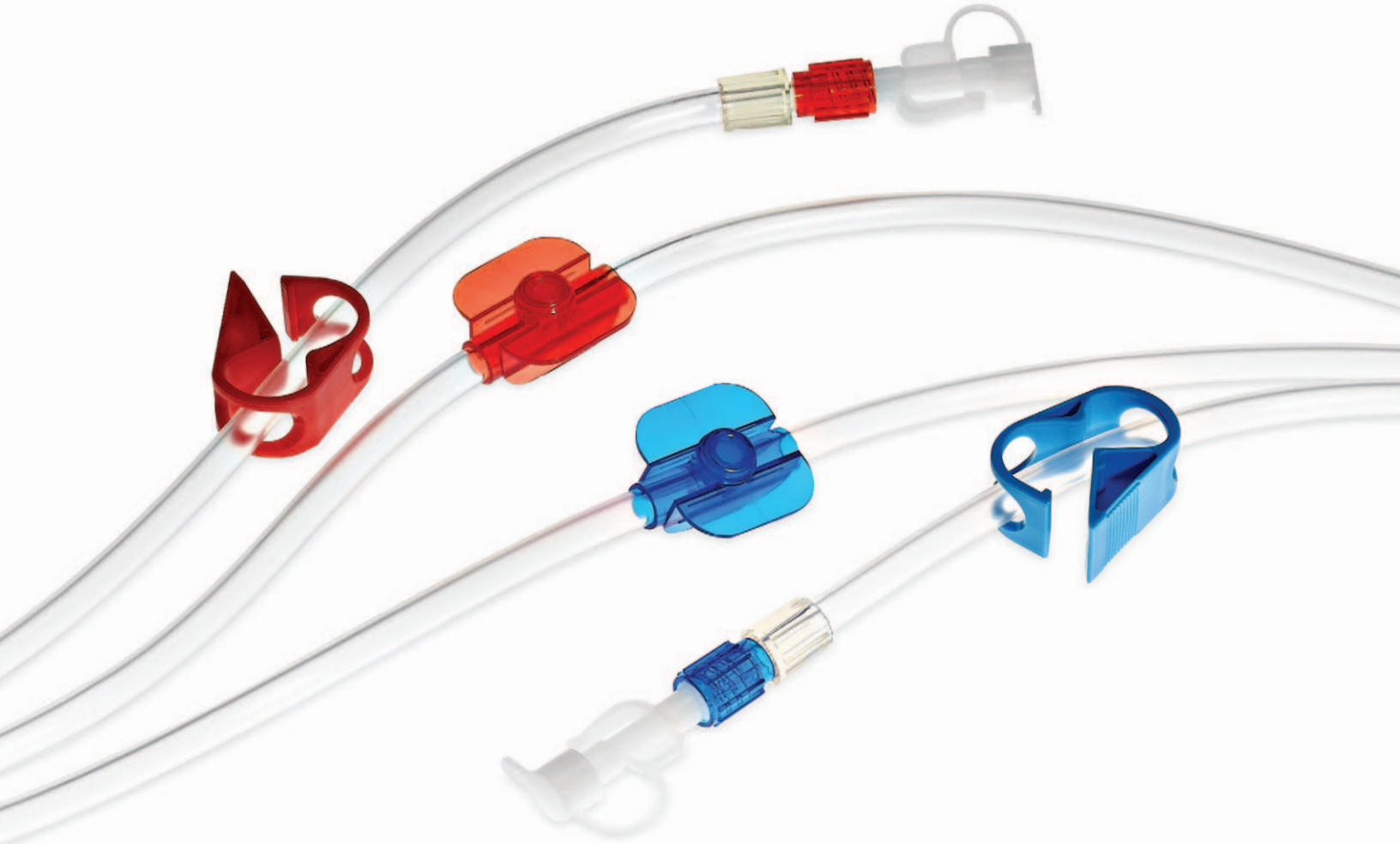
Reserved for Distributor Information in the future.

Ver. 2017-05-05

NIPRO

RENAL

NiproSet® Blood Tubing



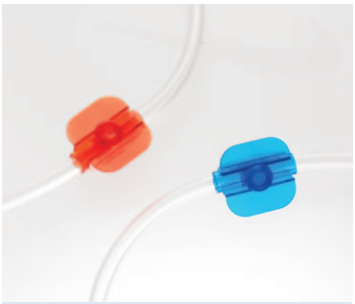
- Built-in safety and efficiency features, with all sets pre-labeled based on equipment compatibility
- Demonstrated accurate and consistent flow rates as well as excellent performance under extreme conditions, when compared with a competitive blood tubing set

NIPRO CONNECT® PROGRAM

Our commitment to strengthen every partnership.

All Nipro renal products are backed by the Nipro Connect Educational Program – offering clinicians product evaluations, in-services, continuing education units (CEU's) and instructional materials.

www.nipro.com



Medication ports

Large finger guard helps protect the user from accidental needle sticks; venous line features multiple medication ports for optimum versatility and choice in medication delivery.

Color-coded clamps

Patient safety is enhanced with clamps that are color-coded for confident identification of the appropriate line.

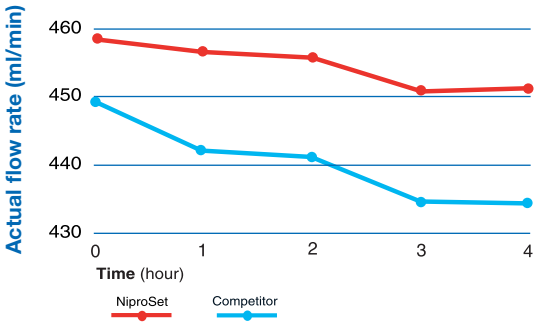
Transducer protectors

Factory-applied torque helps prevent loosening or disconnecting of transducer; engineered to maintain monitoring while decreasing exposure to the dialysis machine.

Drip chambers

Drip chambers feature a versatile medication port and, for an extra measure of safety, are anti-foaming to minimize splashing.

Actual flow rate vs. time
(450 ml/min @ -250 mmHg)



In-vitro testing shows that when compared with a leading brand of blood tubing, NiproSet delivered an accurate and consistent flow rate over time.*

*Data on file

ORDERING INFORMATION

Item #	Description	Packaging
BL+A204/V801	Baxter1000/Baxter Arena/ 8mm/Post-Pump	24/Case (24)
BL+A209Y/V803	Fresenius 2008 series/ 8mm/Pre-Pump	
BL+A210/V803	Fresenius 2008 series/8mm/ Post-Pump	
BL+A211/V804	Baxter 550-1550/8mm/ Post-Pump	

Item #	Description	Packaging
BL+A214Y/V805	Fresenius 2008 series/8mm/ No Arterial Chamber	24/Case (24)
BL+A217Y/V806	B. Braun Dialog/8mm/ Post-Pump	
BL+A223Y/V809	Fresenius 2008 series/8mm/ Pre-Pump/Pre-Attached Priming Set	

CAUTION: Federal law restricts these devices to sale by or on the order of a physician.

NIPRO MEDICAL CORPORATION
200 Crossing Blvd., Bridgewater, NJ 08807
T: +1 (908) 393-7030, F: +1 (908) 393-7031
www.nipro.com

Tab #6 Immediate Package Label

Figure 1 BAIN-BL-001E

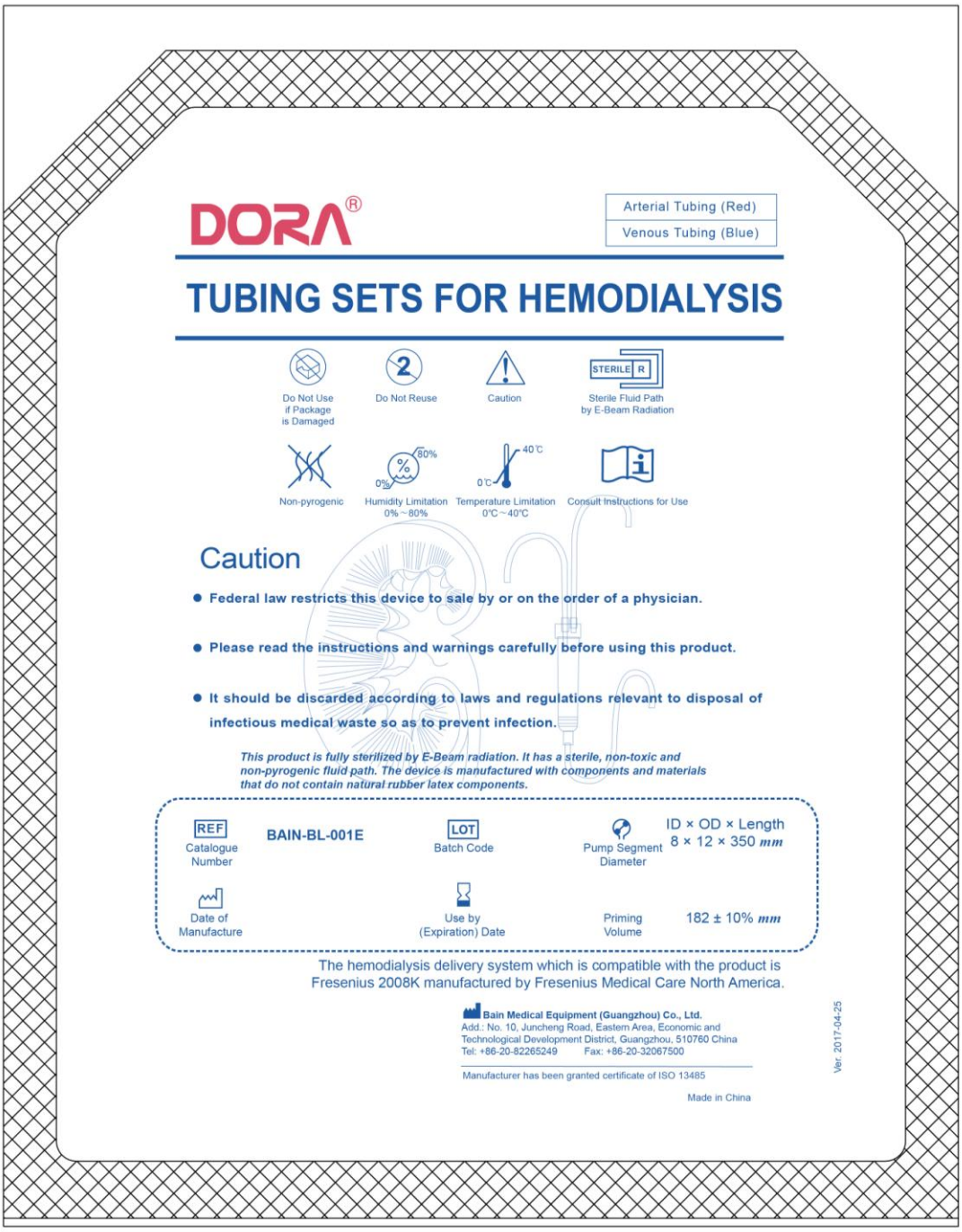


Figure 2 BAIN-BL-002E

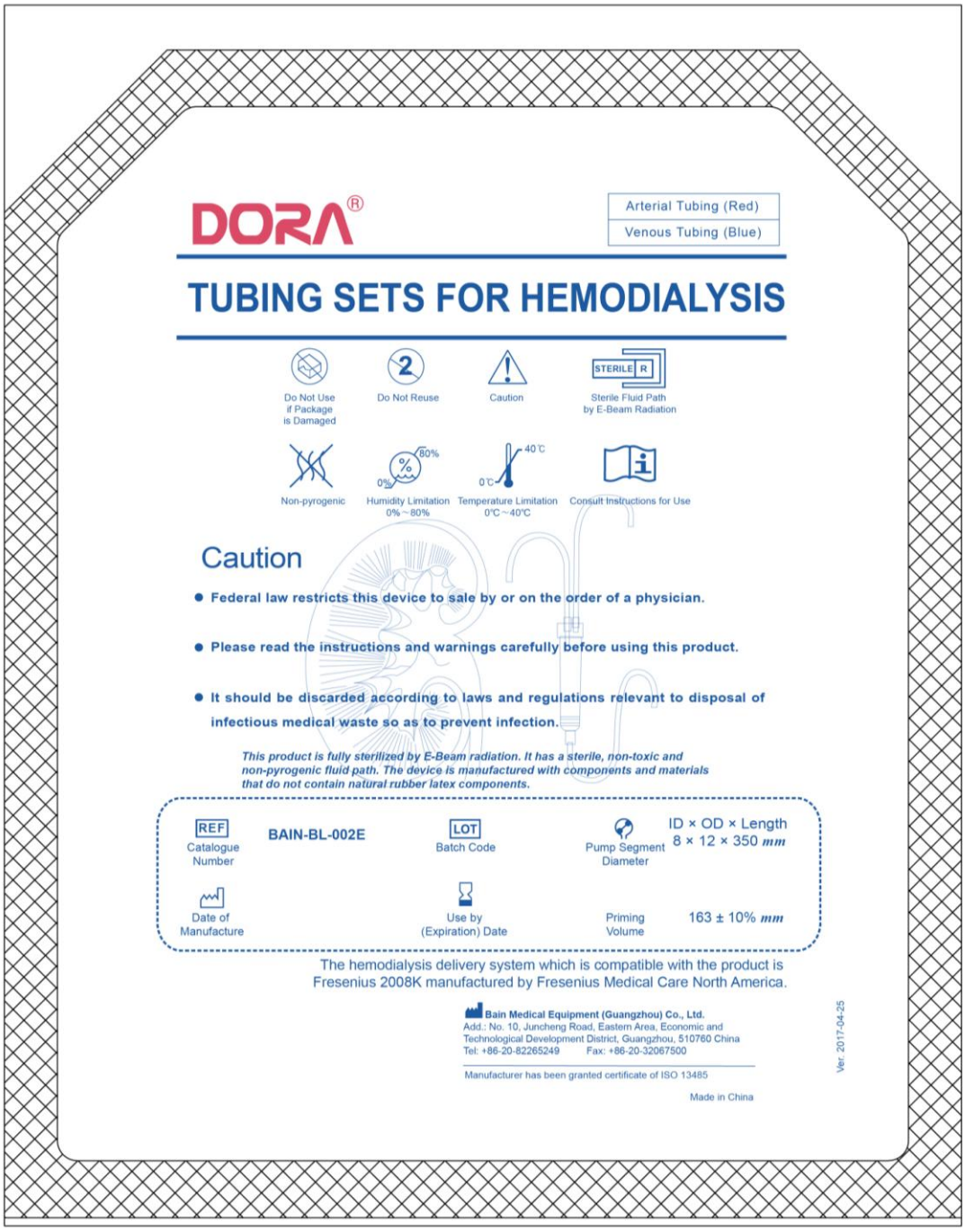


Figure 3 BAIN-BL-003E

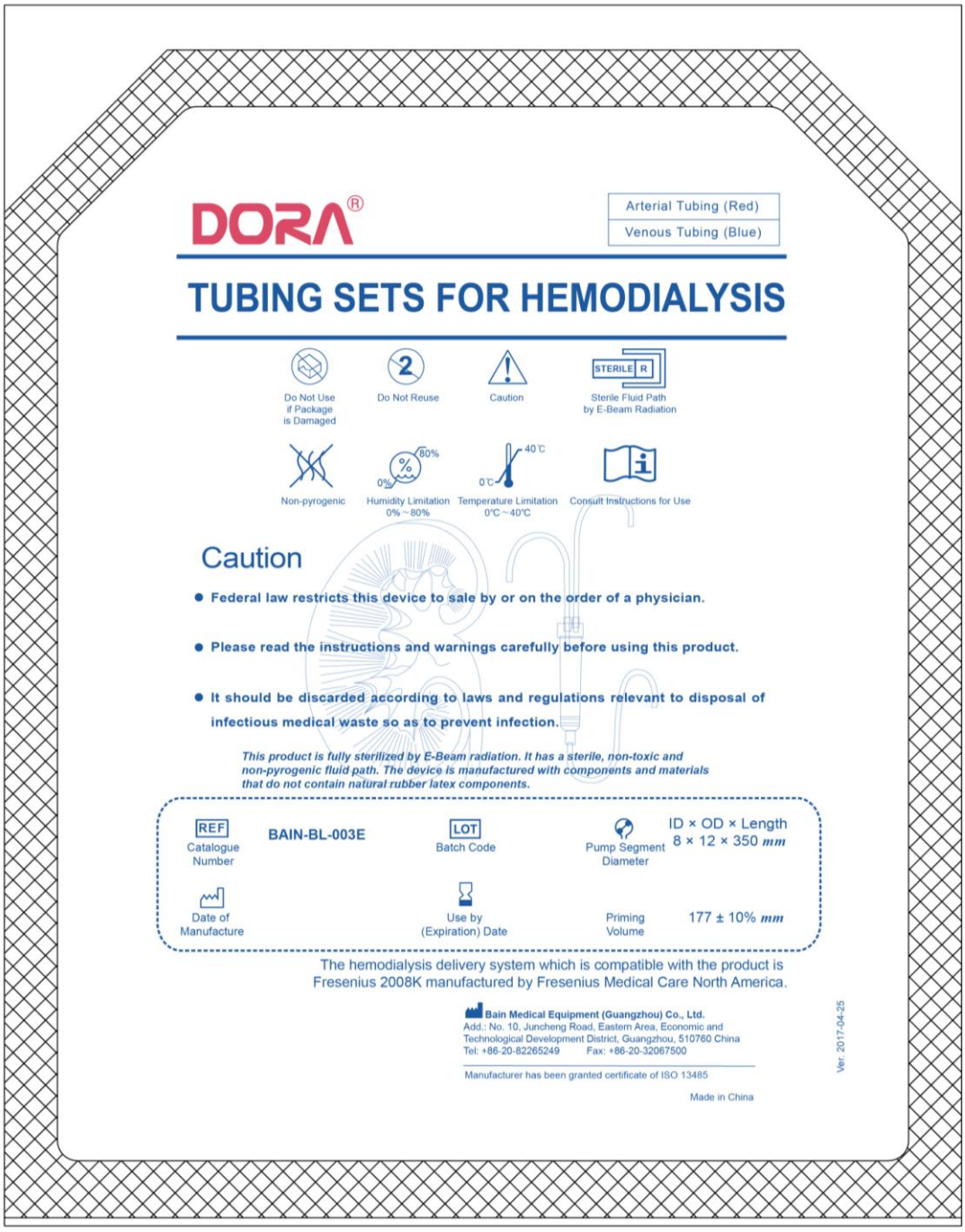


Figure 4 BAIN-BL-004E

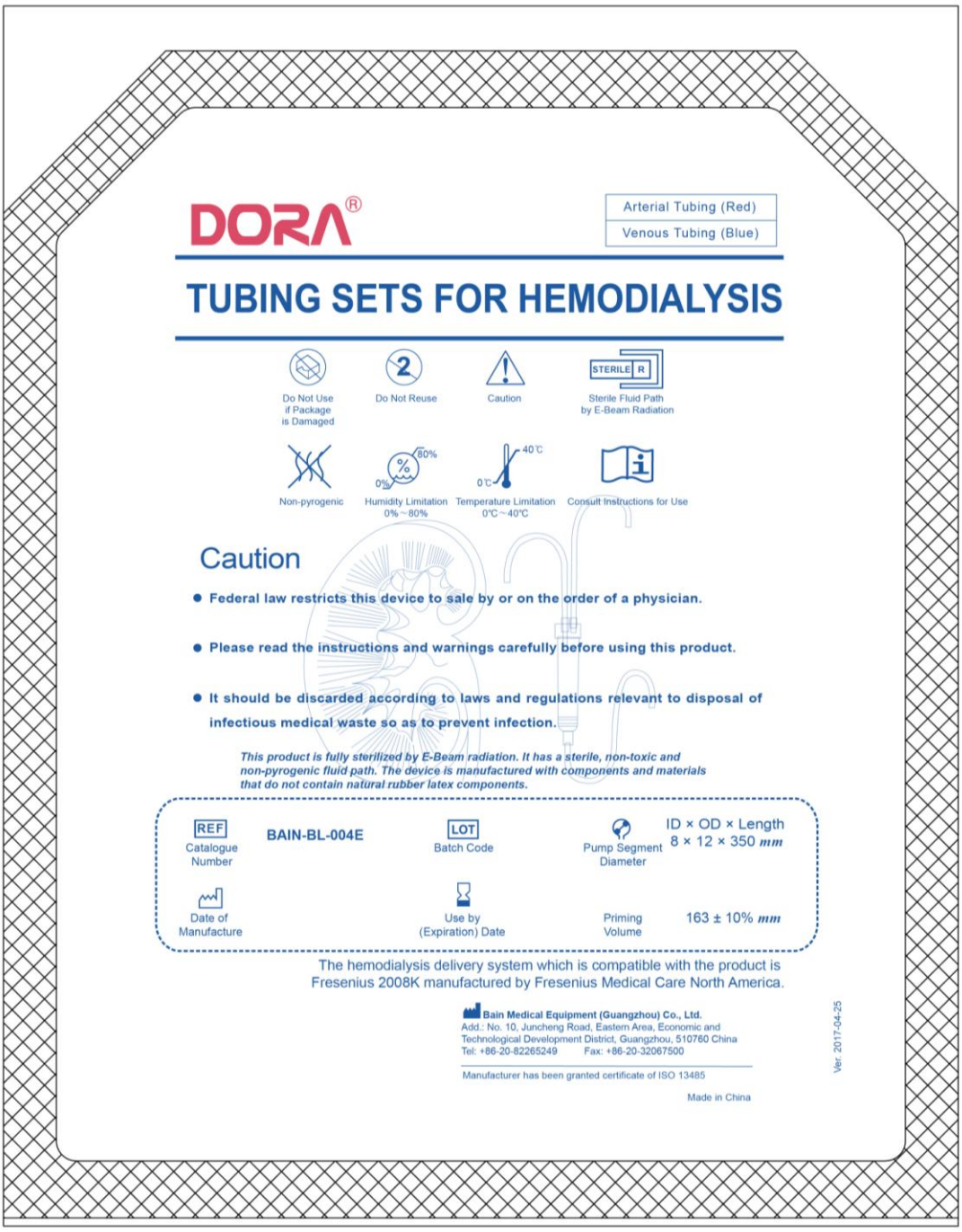
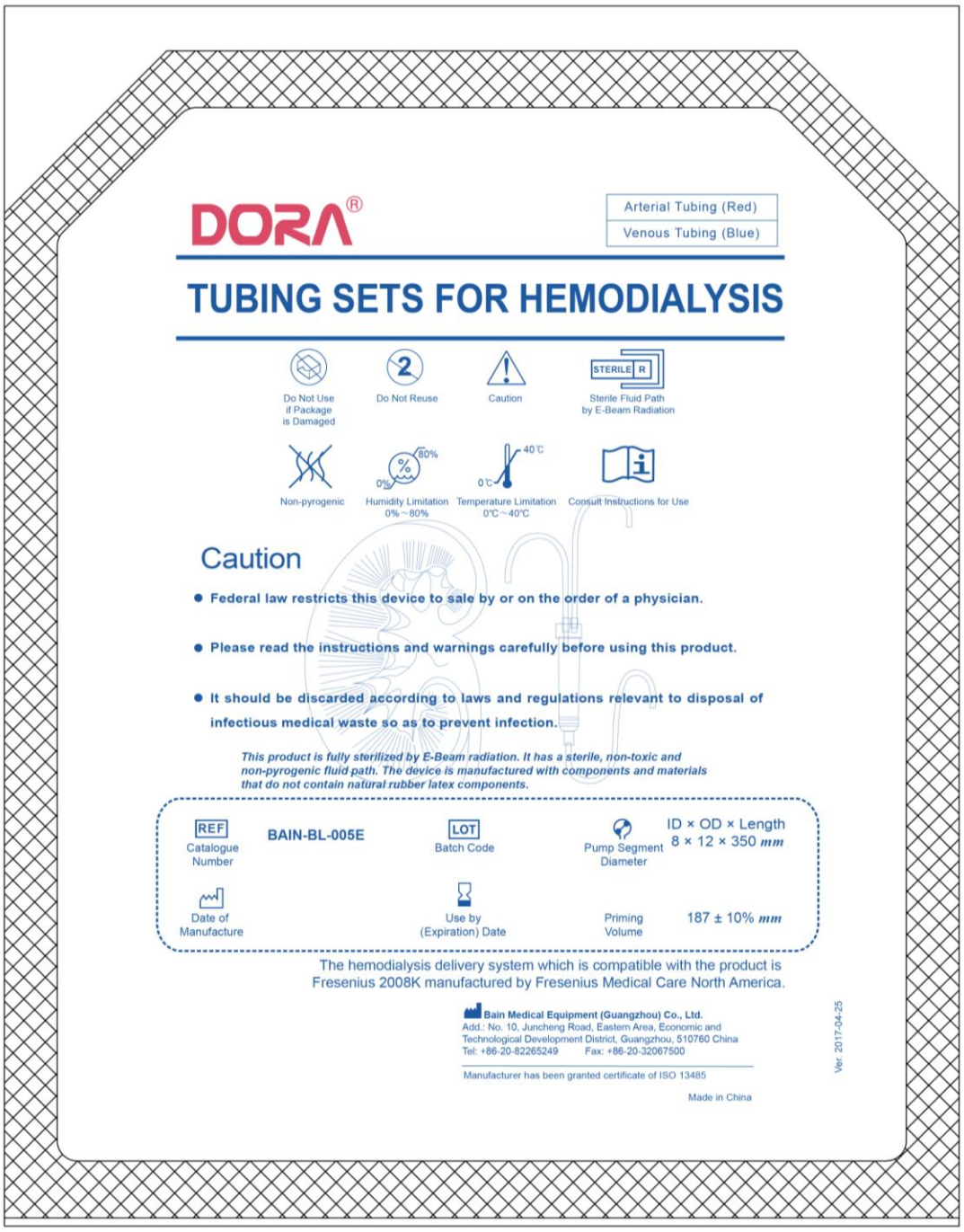


Figure 5 BAIN-BL-005E



Model	(b) (4)
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(b)(4) Engineering Drawings

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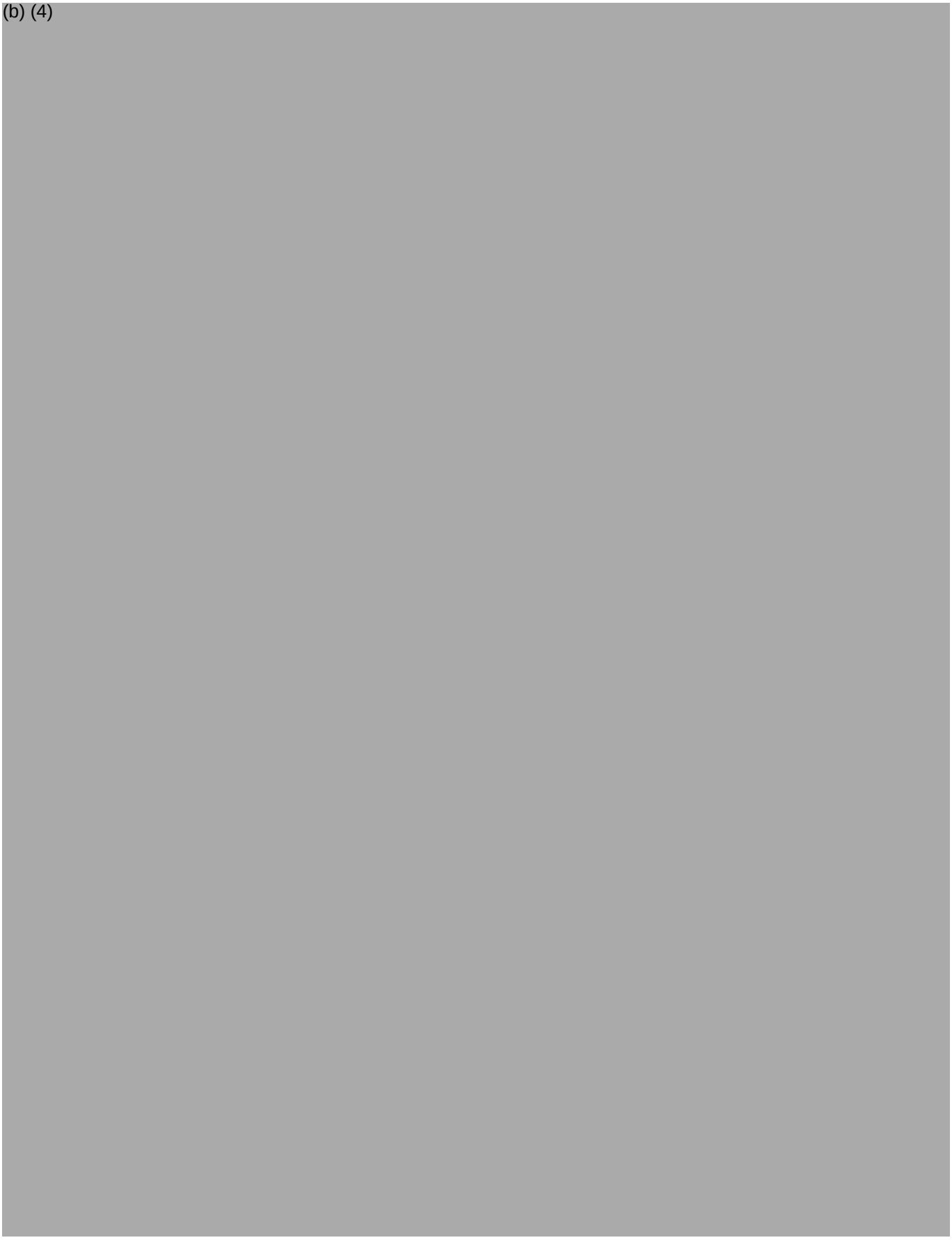
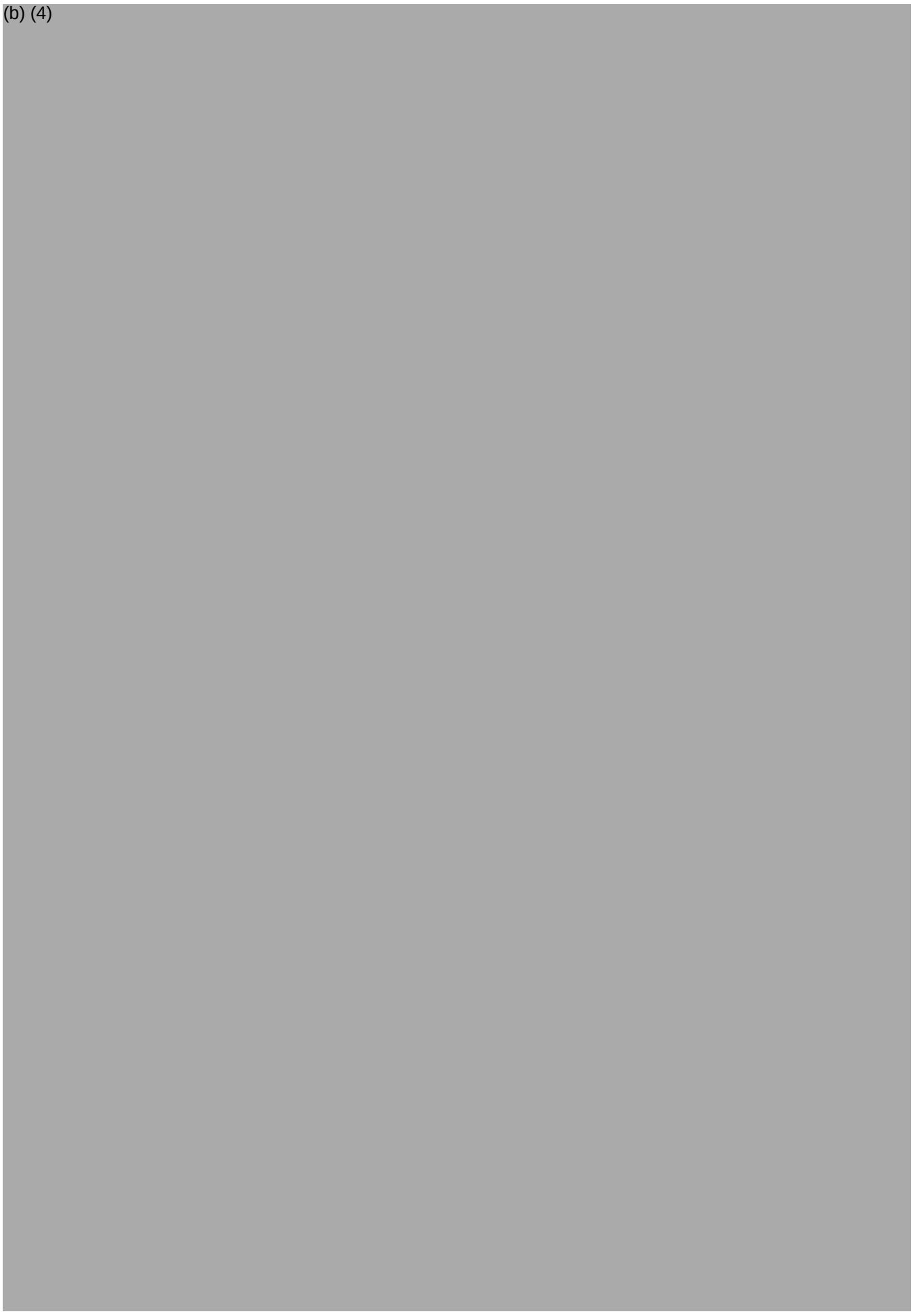
(b)(4) Engineering Drawings

Tab #8 Components Description and Devices Drawings

(b) (4)



(b) (4)



(b) (4)

2. Devices Assemble Drawings

(b) (4)

(b)(4) Assembly Drawings

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