

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K200167

Device Name
QuickClot Control+® Hemostatic Dressing

Indications for Use (Describe)
QuickClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

SECTION 5: 510(k) SUMMARY (K200167)

510(k) Number:

Submitter: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

Contact Person: Soraya King, Director Regulatory Affairs

Preparation Date: 21 January 2020

Trade/Device Name: QuikClot Control+® Hemostatic Dressing

Regulatory Description and Classification: Common Name: Temporary, Internal Use Hemostatic Wound Dressing
Generic Name: Non-absorbable, hemostatic gauze for temporary internal use.
Device Classification: Class II
Regulation Number: 21 CFR §878.4454
Product Code: POD

Predicate Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (DEN160012, cleared as D2 Dressing)

Reference Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (K140757, cleared as D2 Dressing)

Indications for Use: QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Device Description: QuikClot Control+® Hemostatic Dressing is a prescription use non-absorbable device containing kaolin (hemostatic agent) bound to gauze. The hemostatic dressings are x-ray detectable and are provided as a single-use sterile device available in various sizes. The device is available in single or multipacks.

Special Controls: Device complies with the requirements as per 21 CFR 878.4454 for non-absorbable, hemostatic gauze for temporary internal use.

Mechanism of Action: The QuikClot Control+® Hemostatic Dressings are packed into or on the wound and pressure is applied. Pressure is maintained until the bleeding is controlled and may be left in place up to 48 hours. More

510(k) Summary

Z-Medica, LLC QuikClot Control+® Hemostatic Dressing – Line Extension

than one QuikClot Control+® hemostatic dressing can be used. Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression.

Summary of Technological Characteristics:

The fundamental scientific and technological characteristics of the modified device are identical to the predicate (DEN160012). The key characteristics are as follows:

- Mechanism of Action
- Materials of Construction
- Formulation
- Packaging Materials
- Sterilization Method
- Performance Specifications
- Indications/Intended Uses

Performance Testing:

The QuikClot Control+® Hemostatic Dressing complies with the special controls identified in 21 CFR 878.4454. All of the size offerings are the manufactured with the same exact materials and formulation. The device meets the following performance specifications:

- Biocompatibility as per ISO 10993-1 for a device with prolonged patient contact duration (>24 hours to 30 days) for external communicating device with tissue/bone/dentin contact.
 - Cytotoxicity (L929 Neutral Red Uptake Method)
 - Irritation (Intracutaneous Injection)
 - Sensitization (Guinea Pig Maximization Sensitization Test)
 - Systemic Injection (Intravenous Injection and Intraperitoneal Injection – Acute Systemic Toxicity)
 - Implantation (Rabbit Implantation Tests – Tissue, Muscle, and Bone)
 - 4-week implantation study in subcutaneous tissue
 - 1-week implantation study in muscle
 - 4-week implantation study in muscle
 - 4-week implantation study in bone
 - 8-week implantation study in bone
 - Genotoxicity
 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
 - Chromosomal Aberration Study in Mammalian Cells
 - Peripheral Blood Micronucleus Study in Mouse
 - Additional Supporting Tests
 - Carcinogenicity (Clonal Transformation Assay using SHE Cells for 7-days)
 - Repeat Exposure System Toxicity for Kaolin (6-month animal survival study, custom test)
 - Systemic Intravenous Injection for Kaolin Extract
 - Systemic Intraperitoneal Injection for Kaolin Extract

510(k) Summary

Z-Medica, LLC QuikClot Control+® Hemostatic Dressing – Line Extension

▪ Pyrogen Test

- X-Ray Detectable Material - meets required specifications.
- Bench – the device meets the required specifications and acceptance criteria for tensile strength, elongation, clotting, and kaolin release.
- Preclinical Animal Study – Three GLP large animal (swine), to include a survival model, and one non-GLP study demonstrated the safety and effectiveness of QuikClot Control+. The studies included assessments such as hemostasis. In addition to hemostasis assessments, the animal survival study also conducted evaluations for blood chemistry (hematology, serum, coagulation), and macroscopic and microscopic tissue/organ examinations (adhesion, thromboembolism, kaolin migration). The cumulative animal study results support the safety and efficacy of the device.
- Stability – testing supports a 39-month expiration date.

Conclusion

The subject devices are identical to the predicate in terms of materials of construction, hemostatic agent used, mode of operation, scientific technological characteristics, indications for use and intended uses. Same as the predicate device, the new size options will be provided sterile utilizing existing validated packaging systems. The additional size offerings do not raise new types of questions of safety and effectiveness and is substantially equivalent to the predicate device.

SECTION 8: FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

Not applicable.



April 23, 2020

Z-Medica, LLC
Soraya King
Director, Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K200167

Trade/Device Name: QuikClot Control+
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: March 26, 2020
Received: March 27, 2020

Dear Soraya King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.

Acting Assistant Director

DHT4B: Division of Infection Control
and Plastic Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

From: Mason, Tiffani * [Tiffani.Mason@fda.hhs.gov]
Sent: 1/24/2020 7:45:31 PM
To: sking@z-medica.com
Subject: K200167 Acknowledgement Notification
Attachments: K200167 Acknowledgment Letter.pdf

Tiffani R. Mason
Tiffani.Mason@fda.hhs.gov
Record Management Specialist 1 DCC 510K



Acknowledgment Letter

1/24/2020

Soraya King, Director, Regulatory Affairs
Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492
UNITED STATES

Dear Soraya King:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K200167
Received: 1/23/2020
Applicant: Z-Medica, LLC
Device: QuikClot Control+

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

QuikClot Control+ 12x12 3-ply Dressing

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Lab Number

(b)(4)

(b)(4)

GLP Report

Page 1 of 21

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Attachment 4: Sensitization Test, Page 24 of 32

GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

(b)(4)

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Section 1: User Fee and Payment Receipt, Page 1 of 4

Records processed under FOIA Request 2023-0469. Released by CDRH on 04-09-2024

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: <div style="border: 1px dashed black; padding: 2px; display: inline-block;">(b)(4)</div> Write the Payment Identification number on your check.
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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:
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) Z-MEDICA LLC 4 Fairfield Blvd Wallingford CT 06492 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2922	2. CONTACT NAME Sheila Wallin 2.1 E-MAIL ADDRESS swallin@z-medica.com 2.2 TELEPHONE NUMBER (include Area code) 203-294-0000 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 203-294-0688
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3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>

Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice <input type="checkbox"/> De Novo Request	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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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 NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD208319

Section 1: User Fee and Payment Receipt, Page 2 of 4

Records processed under FOIA Request 2023-9460; Released by CDRH on 04-09-2024

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?

YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> 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 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
 Paper Reduction Act (PRA) Staff
 PRASStaff@fda.hhs.gov

[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)

20-
Jan-2020

Records processed under FOIA Request 2023-9460; Released by CDRH on 04-09-2024

["Close Window"](#) [Print Cover sheet](#)

Section 1: User Fee and Payment Receipt, Page 3 of 4

From: notification@pay.gov
To: [King, Soraya](#)
Subject: Pay.gov Payment Confirmation: FDA User Fees
Date: Monday, January 20, 2020 6:26:18 PM

Section 1: User Fee and Payment Receipt, Page 4 of 4

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact FDA User Fees at (301) 796-7200.

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4)
Agency Tracking ID: (b)(4)
Transaction Type: Sale
Transaction Date: Jan 20, 2020 6:26:12 PM

Account Holder Name: SORAYA KING

(b)(4)

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

FDA's Email Request (dated 24 March 2020) – FDA reviewer Ramesh Kapil Panguluri Ph.D.

Major Deficiency List

(b)(4)

(b)(4)

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April 23, 2020</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Panguluri Ramesh.</p>

<p>*** This is a system-generated email notification ***</p>

February 7, 2020</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your premarket notification (510(k)) K200167, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Panguluri Ramesh.</p>

<p>*** This is a system-generated email notification ***</p>

GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

CONFIDENTIAL

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

TEST ARTICLE NAME

QuikClot Control+ 12x12 3-ply Dressing

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Lab Number

(b)(4)

(b)(4)

GLP Report

Page 1 of 13

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Attachment 5: Acute Systemic Toxicity Test, Page 16 of 22

GLP PROTOCOL

TEST FACILITY

SPONSOR

(b)(4)

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

(b)(4)

(b)(4)
GLP PROTOCOL

Page 1 of 7

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SECTION 14: PRODUCT LABELING

An example of the product labeling is included as **Attachment 10** – Draft Package Label, and **Attachment 11** – Draft Instructions for Use (IFU)/Package Insert.

The instructions for use of the subject device are identical to the predicate device. The indications for use, contraindications, warnings, precautions and directions of use remain the same.

Z-MEDICA

It's QuikClot Or It's Not

K200167

23 January 2020

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

JAN 24 2020

RECEIVED

Attention: Cynthia Chang, Ph.D., Director, Division of Health Technology 4B (Infection Control & Plastic Surgery Devices).

Re: **510k #K200167 – eCopy Replacement**
Traditional 510(k) Premarket Notification for Z-Medica, LLC's QuikClot Control+® Hemostatic Dressing – Line Extension for Additional Size Offering

Dear Dr. Chang,

(b)(4)

Z-Medica, LLC is providing one (1) ecopy replacement of the entire submission with this signed ecopy replacement cover letter. This signed ecopy replacement cover letter is the only paper document included with this resubmission. All supporting information, to include a copy of the signed ecopy replacement cover letter, are included in the USB drive. The copy of this cover letter is provided as **Attachment 12** and a copy of the FDA eCopy Hold Notification is included as **Attachment 13**.

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, Z-Medica, LLC is submitting this Traditional 510(k) Premarket Notification, prior to commercial distribution, for clearance of additional size options of our QuikClot Control+® Hemostatic Dressing (DEN160012 wherein the device was referred to as D2 Dressing). The currently cleared indications for use and intended uses, DEN160012, will remain the same. The new size options do not represent a change in technological characteristics, principles of operation, safety, or effectiveness of the device.



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(b)(4)

Z-Medica, LLC is FDA registered as a Small Business under decision number SBD208319. Therefore, in accordance with Medical Device User Fee and Modernization Act of 2002 (MDUFA), Z-Medica, LLC has submitted the required application fee of **(b)(4)** (FY 2020 MDUFA User Fees). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

As per FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s (13 September 2019)*, the principal factors about the design and use of the additional QuikClot Control+® size offering comply with the following:

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

^AA device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

This submission contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.

Z-MEDICA

It's QuikClot Or It's Not

The official contact person for this submission is the undersigned. Thank you in advance for the review of this submission.

Respectfully submitting,

(b)(6)

Soraya King
Director, Regulatory Affairs
Z-Medica, LLC
Cell: **(b)(6)**
Office: 203-774-7922



Z-MEDICA

It's QuikClot Or It's Not

FDA/CDRH/DCC

JAN 23 2020

RECEIVED

K200167

21 January 2020

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Cynthia Chang, Ph.D., Director, Division of Health Technology 4B (Infection Control & Plastic Surgery Devices).

Re: Traditional 510(k) Premarket Notification for Z-Medica, LLC's QuikClot Control+® Hemostatic Dressing – Line Extension for Additional Size Offering

Dear Dr. Chang,

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, Z-Medica, LLC is submitting this Traditional 510(k) Premarket Notification, prior to commercial distribution, for clearance of additional size options of our QuikClot Control+® Hemostatic Dressing (DEN160012 wherein the device was referred to as D2 Dressing). The currently cleared indications for use and intended uses, DEN160012, will remain the same. The new size options do not represent a change in technological characteristics, principles of operation, safety, or effectiveness of the device.

(b)(4)

Z-Medica, LLC is FDA registered as a Small Business under decision number SBD208319. Therefore, in accordance with Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Z-Medica, LLC has submitted the required application fee of **(b)(4)** FY 2020 MDUFA User Fees). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

As per FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (13 September 2019), the principal factors about the design and use of the additional QuikClot Control+® size offering comply with the following:



Z-MEDICA

It's QuikClot Or It's Not

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

^AA device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Z-Medica, LLC is providing one (1) copy of this submission with this signed cover letter as per the *eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff* dated 16 December 2019. The signed cover letter is the only paper document included with this submission. All supporting information, to include an copy of the signed cover letter, are included in the USB drive.

This submission contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.

The official contact person for this submission is the undersigned. Thank you in advance for the review of this submission.

Respectfully submitting

(b)(6)

Soraya King
 Director, Regulatory Affairs
 Z-Medica, LLC
 Cell: **(b)(6)**
 Office: 203-774-7922

Z-MEDICA®		QuikClot Control+® 39 Months Real Time Stability Study Report	
Document No.:	(b)(4)	Revision Date:	12/20/2018
Prepared by:		Title:	(b)(4)
Sections Changed in the Current Revision			
12/20/2018: Initial Release			
DCR#	(b)(4)	DCR Approval Date	12/20/2018

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Attachment 9: 39-Month Real Time Stability Study

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Section 2: CDRH Premarket Review Submission Cover Sheet

Records processed under E.O. 13526, 2013-08-14
 FOOD AND DRUG ADMINISTRATION

409-2021 approval
 OMB No. 0910-0120
 Expiration Date: June 30, 2020
 See PRA Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 21 January 2020	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Z-MEDICA, LLC	Establishment Registration Number (if known) 3004138549		
Division Name (if applicable)	Phone Number (including area code) 203-9806-067		
Street Address 4 FAIRFIELD BOULEVARD	FAX Number (including area code) 800-406-1347		
City WALLINGFORD	State / Province CT	ZIP/Postal Code 06492	Country USA
Contact Name SORAYA KING			
Contact Title Director, Regulatory Affairs		Contact E-mail Address sking@z-medica.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
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	

Section 2: CDRH Premarket Review Submission Cover Sheet

SECTION D1			REASON FOR APPLICATION - PMA, PDR, OR IDE
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager	
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment	
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address	
<input type="checkbox"/> Other Reason (<i>specify</i>):			

SECTION D2			REASON FOR APPLICATION - IDE
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent/Applicant <input type="checkbox"/> Design/Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing	
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final			
<input type="checkbox"/> Other Reason (<i>specify</i>):			

SECTION D3			REASON FOR SUBMISSION - 510(k)
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology	
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Product line extension to include additional size options.			

Section 2: CDRH Premarket Review Submission Cover Sheet

SECTION E ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	2	3	4	
5	6	7	8	

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

#	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K140757	QuikClot Control+®	Z-Medica, LLC
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Non-absorbable, hemostatic gauze for temporary internal use

#	Trade or Proprietary or Model Name for This Device	Model Number
1	QuikClot Control+®	1
2		2
3		3
4		4
5		5

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

(b)(4)	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 POD	C.F.R. Section (if applicable) 21 C.F.R. 87804454	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

Indications (from labeling)
 QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Section 2: CDRH Premarket Review Submission Cover Sheet

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		Records processed under FOIA Request 2023-9460, Released by CDRH on 04-09-2024	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 3004138459	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Z-MEDICA, LLC		Establishment Registration Number 3004138549	
Division Name (if applicable)		Phone Number (including area code) <div style="border: 1px dashed black; padding: 2px; display: inline-block;">(b)(6)</div>	
Street Address 4 FAIRFIELD BOULEVARD		FAX Number (including area code) 800-406-1347	
City WALLINGFORD	State / Province CT	ZIP Code 06492	Country USA
Contact Name SORAYA KING		Contact Title Director, Regulatory Affairs	Contact E-mail Address sking@z-medica.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> 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
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> 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

Section 2: CDRH Premarket Review Submission Cover Sheet

SECTION I

Records processed under **UTILIZATION OF STANDARDS** by CDRH on 04-09-2024

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	TIR13004	ANSI/AAMI/ISO	Sterilization of Health Care Products – Radiation – Substantiation of a Selected Sterilization Dose: Method VDmaxSD	2013	
2	D5035-11	ASTM	Standard Test Method for Breaking Force and Elongation of Textile Fabrics	2019	
3	F88/F88M-15	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials	2015	
4	F 640-07	ASTM	Standard Test Methods for Determining Radiopacity for Medical Use		
5	F1140-07	ASTM	Internal Pressurization Failure Resistance of Unrestrained Packages		
6	F1980-16	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.		
7	F2096-11	ASTM	Method B, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)		

Refer to Section 9, Declarations of Conformity and Summary Reports for a complete list of Standards.

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.

SECTION 9: DECLARATION OF CONFORMITY AND SUMMARY REPORTS

Z-Medica, LLC is including this statement that the QuikClot Control+® Hemostatic Dressings comply with the below listed recognized consensus standards:

- ANSI/AAMI/ISO TIR13004:2013, Sterilization of Health Care Products – Radiation – Substantiation of a Selected Sterilization Dose: Method VD_{max}^{SD}.
- ASTM D5035-11(2019), Standard Test Method for Breaking Force and Elongation of Textile Fabrics.
- ASTM F88/F88M-15, Seal Strength for Flexible Barrier Materials.
- ASTM F 640-07, Standard Test Methods for Determining Radiopacity for Medical Use.
- ASTM F1140-07, Internal Pressurization Failure Resistance of Unrestrained Packages.
- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM F2096-11 Method B, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test).
- BS EN ISO 14971:2012, Medical Devices – Application of Risk Management to Medical Devices.
- ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process.
- ISO 10993-3:2003, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity.
- BS EN ISO 10993-3:2009, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity.
 - Note: Identical to ISO 10993-3:2003.
- ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.
- ISO 10993-6:2007, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation.
- BS EN ISO 10993-6:2009, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation.
 - Note: Identical to ISO 10993-6:2007.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
- BS EN ISO 10993-11:2018, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
 - Note: Identical to ISO 10993-11:2017.

SECTION 9: DECLARATION OF CONFORMITY AND SUMMARY REPORTS

- ISO 10993-11:2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
- BS EN ISO 10993-11:2009, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
 - Note: Identical to ISO 10093-11:2006.
- ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.
- ISO 11137-1:2006/R2015 & A1:2013 & A2:2019, Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.
- ISO 11137-2:2013, Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose.
- ISO 11607-1, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [includes Amendment 1 (2014)].
- ISO 11737-1:2018, Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product.
- ISO 11737-2:2009/R2014, Sterilization of Medical Devices – Microbiological Methods – Part 2: Sterilization Process for Medical Devices.
- ISTA 2A, Pre-Shipment Testing Procedures – Combination Tests for Packaged Products Weighing 150 lbs. (68kg) or less.

SECTIONS 10: DEVICE DESCRIPTION

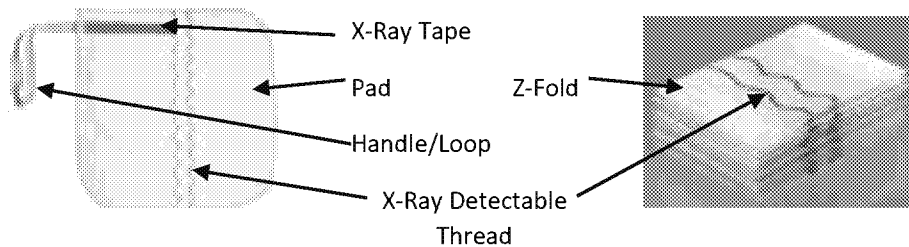
A. Device Description

QuikClot Control+® Hemostatic Dressing is a prescription use non-absorbable device comprised of non-woven gauze (b)(4) that is impregnated with a mixture of (b)(4) grade kaolin (b)(4).

(b)(4) The binder does not breakdown easily supporting the de minimis release of kaolin. The hemostatic dressing contains x-ray detectable thread and is provided as a single-use, sterile device available in various configurations (length, width, plies, pad, z-fold, folded, cotton handle/loop, and x-ray tape) and sizes (including 2" x 2", 5" x 5", 8" x 8", 12" x 12", 3" x 4 yds, and 4" x 4" yds). All patient contacting layers of the dressing are coated with the kaolin (b)(4). The device is designed to conform readily to the wound and can be left in the body for up to 48 hours. Refer to **Figure 1** for product depiction examples.

QuikClot Control+® was first FDA cleared via 510(k) #K140757 for external use for temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries. The indications were expanded to include control of Class III and Class IV bleeding from internal organ space (DEN160012). The device was cleared under the project name (b)(4) and commercialized using the brand name QuikClot Control+®. Refer to **Attachment 1** and **2** for a copy of the FDA clearance letters.

Figure 1: Images of Cleared QuikClot Control+® Hemostatic Dressing Configurations



The formulation and product performance specifications of QuikClot Control+® are the same as described in DEN160012 (b)(4)

(b)(4)
(b)(4) Refer to **Table 1** for product formulation, **Table 2** for optional design features, and **Table 3** for product specifications.

Table 1: QuikClot Control+® Hemostatic Dressing Formulation

Material	Specification
Gauze Substrate	(b)(4)
X-Ray Detectable Thread	
Kaolin	
(b)(4)	

Table 2: QuikClot Control+® Hemostatic Dressing Optional Materials

Material	Specification
X-Ray Detectable Tape	(b)(4)
Handle/Loop	
Thread	
(b)(4)	

Table 3: QuikClot Control+® Hemostatic Dressing Performance Specifications (tested post coating)

Property	Specification
(b)(4)	(b)(4)
Color	
Machine Direction (MD) Tensile	
MD Elongation	
Cross Direction (CD) Tensile	
CD Elongation	
Kaolin Release Test	

B. Indications for Use

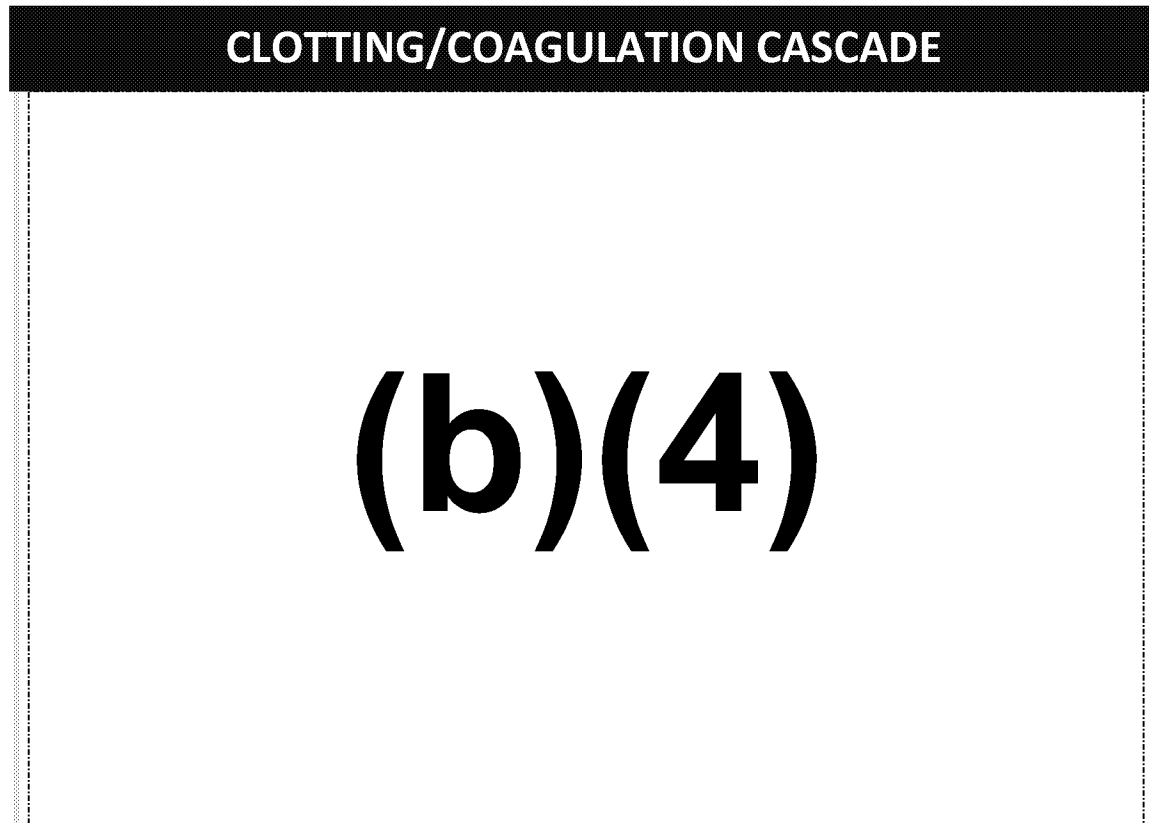
QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

C. Principles of Operation and Technological Characteristics

The QuikClot Control+® Hemostatic Dressings achieve bleeding control through the application of physical compression, which slows the flow of blood from the wound and absorption of blood by the non-woven gauze, along with the kaolin’s promotion of the body’s natural clotting cascade/coagulation cascade process via the ‘contact activation (intrinsic) pathway’. The hemostatic dressing is packed into or on the wound and compression is applied. More than one dressing may be required and/or additional dressings applied to maintain compression. **(b)(4)**

(b)(4)

Figure 2: Clotting (Coagulation) Cascade – Mechanism of Action for QuikClot Control+®



¹ Lamb KM, Pitcher HT, Cavarocchi NC, Hirose H. Vascular site hemostasis in percutaneous extracorporeal membrane oxygenation therapy. *Open Cardiovasc Thorac Surg J.* 2012;5:8-10.

² Schmaier AH (2008) This Elusive Physiologic Role of Factor XII. (Translated from eng) *J Clin Invest* 118(9):3006-3009 (in eng).

³ Samuel M, Pixley RA, Villanueva MA, Colman RW, & Villanueva GB (1992) Human Factor XII (Hageman Factor) Autoactivation by dextran sulfate. Circular dichroism, fluorescence, and ultraviolet difference spectroscopic studies. (Translated from eng) *J Biol Chem* 267(27):19691-19697 (in eng).

⁴ Colman RW, et al. (1987) Initiation of Blood Coagulation at Artificial Surfaces. (Translated from eng) *Ann NY Acad Sci* 516:253-267 (in eng).

⁵ Random House Kernerman Webster's College Dictionary, © 2010 K Dictionaries Ltd. Copyright 2005, 1997, 1991 by Random House, Inc.

⁶ Dee KC, Puleo DA, Bizios R. An Introduction to Tissue-Biomaterial Interactions. Hoboken, NJ: Wiley & Sons; 2002.

SECTION 11: DESCRIPTION OF PROPOSED DEVICE MODIFICATIONS

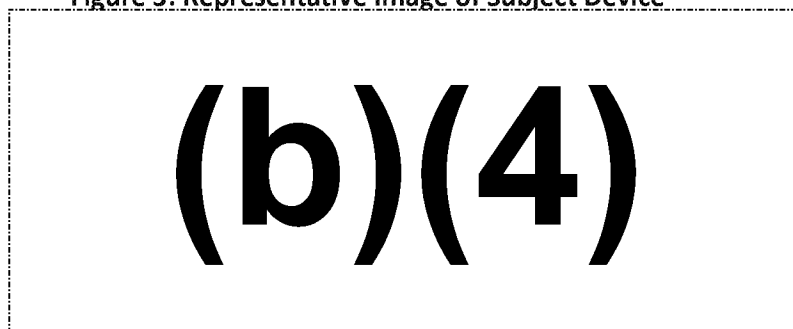
The subject of this premarket notification includes a variety of additional pad sizes. Some examples of new sizes include 1" x 1", 3 ply; 4"x2", 6 ply; 4" x 2", 10 ply; 4"x6", 6 ply; 4"x6", 10 ply; 4" x 8", 6 ply; 4" x 8", 7 ply; 4" x 8", 8 ply; 4" x 8", 9 ply; 4" x 8", 10 ply; and 4" x 12", 9 ply. None of the existing product specifications and product performance criteria were modified to accommodate the subject device (refer to **Table 1**, **Table 2** and **Table 3**). The new configurations are manufactured using the same formulation (kaolin and (b)(4)) and materials of construction (non-woven gauze, x-ray thread, x-ray tape, and (b)(4)) as the predicate (DEN160012). Therefore, the existing product specifications and product performance criteria remain the same for the subject device. The new size options will also be provided as single-use, sterile devices terminally sterilized via gamma radiation using the same applied dose, existing validated packaging systems, and product shelf-life as the predicate.

The only difference between the subject and predicate device is that the inner plies of the new sewn pad configurations are not coated with kaolin and (b)(4) (uncoated gauze substrate remains the same for all plies). The modifications are not in response to adverse events or a result of a corrective action due to recall activities. (b)(4)

(b)(4)

(b)(4) The outer layer/coated surfaces of the impregnated gauze are the portion of the dressing that comes in direct contact with the bleeding injury and instigates the clotting/coagulation cascade. Therefore, the inner plies are not required to be coated to achieve temporary control of class III or class IV internal organ space bleeding, or bleeding due to surgical wounds and traumatic injuries. The inner plies also consist of the same (b)(4) gauze used in the outer surfaces, but are not coated. The new size options do not represent a change in technological characteristics, principles of operation, safety, or effectiveness of the device.

Figure 3: Representative Image of Subject Device



March 24, 2020</br></br><p>We have reviewed your submission. Please see attached. </p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Panguluri Ramesh. </p>

<p>*** This is a system-generated email notification ***</p>

SECTION 13: STERILIZATION, PACKAGING, and SHELF-LIFE

A. Sterilization

The existing sterilization parameters were re-executed to comply with the most current version of ISO 11137-1:2018, Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganism on Product. The scope of the validations covered all QuikClot Hemostatic Dressings (D1) and QuikClot Control+® (D2) generation of products. The validations were performed on pre-determined worst-case configurations from each product generation. The validation activities included dosimetry verification, bioburden and sterility testing. The re-execution confirmed the appropriateness of the existing parameters to ensure a sterility assurance level (SAL) of 10^{-6} . A copy of the report is provided as **Attachment 8**. The data applies to the subject devices as the new configurations are within scope of the worst-case QuikClot Control+® predicate device tested.

B. Packaging

The packaging is comprised of standard industry materials such as foil/film laminates manufactured from (b)(4). The packaging systems were previously validated to ensure the combination of the sterile barrier, protective packaging, packaging materials, and product configurations were appropriate. Moreover, the re-execution of the sterilization parameters, (refer to **Attachment 8**) included the packaging system for QuikClot Control+® (DEN160012). The re-execution confirmed the appropriateness of the packaging configuration and materials. The new configurations do not challenge the existing packaging. The subject device will be commercialized utilizing the existing validated packaging systems.

C. Shelf-Life

A real-time aging study was completed in accordance with applicable standards and as per the protocol provided in DEN160012. The study demonstrated that the packaging system (materials, sizing, sealing parameters) and product configuration maintained packaging integrity. It also confirmed that the device maintained the established product performance specifications and an SAL of 10^{-6} . The study validated that the sterilization parameters, packaging system and product configuration support a 39-month expiration. A copy of the report is included in **Attachment 9**.

The subject devices will be manufactured with the same materials of construction and formulation as the predicate. The new configurations do not represent a new worst-case configuration (no new material or a material type in greater quantity). The subject device will be sterilized using the existing validated parameters and commercialized utilizing the same packaging system as the predicate. The data supports a 39-month shelf-life for the subject device.

GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

CONFIDENTIAL

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

TEST ARTICLE NAME

QuikClot Control+ 12"x12" (P/N 4030)

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Lab Number

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(b)(4)

GLP Report

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(b)(4)

Attachment 6: QuikClot Control+ Pyrogen Test, Page 14 of 24

GLP PROTOCOL

TEST FACILITY

SPONSOR

(b)(4)

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

SECTION 6: PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 5807.87(k)]

I certify that, in my capacity as (the position held in company) of Z-Medica, LLC, 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.

(b)(6)

Signature

DINA DUBEY , CHIEF OPERATING OFFICER
Typed Name and Title

1/21/2020

Date

(Premarket Notification [510(k)] number)



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K200167 Date Received by DCC: Jan 24, 2020

Lead Reviewer: Kapil Panguluri, PhD

Center: CDRH Office: OHT 4 Division: DHT4B

Decision:

- Accept. If Accept, notify submitter.
- Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions			
Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
<p>1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i></p> <p>If the product does not appear to be a device or such a combination product, mark "No."</p>	☒	☐	
Comments:			
<p>2 Is the submission with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i></p> <p>If submission should not be reviewed by your Center mark "No."</p>	☒	☐	
Comments:			

<p>3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i></p> <p>If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments:</p>			
<p>4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)?</p> <p>If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments:</p>			
<p>5 Is this device type eligible for a 510(k) submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p>Comments:</p>			
<p>6 Is there a pending PMA for the same device with the same indications for use?</p> <p>If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<p>Comments:</p>			
<p>7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action.</p> <p>If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments:</p>			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3) All pages of the submission are numbered. <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. <small>Records processed under FOIA Request 2023-9460. Released by CDRH on 04-09-2024</small> *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download):				<input type="checkbox"/>	
a) Device trade/proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance " Alternative to Certain Prescription Devices Labeling Requirements ," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements .) See recommended format (https://www.fda.gov/media/86323/download).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
4) Submission contains a 510(k) Summary or 510(k) Statement.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l). See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
6) Submission is a Class III 510(k) device.	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7) Submission contains clinical data	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). This includes both FDA-recognized and non-recognized consensus standards.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
a) The submission cites FDA-recognized voluntary consensus standard(s).	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance " Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices ," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices . OR If citing general use of a standard as noted in FDA's guidance " Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices ," the basis of such use is included along with the underlying information or data that supports how the standard was used.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
i) The basis of use is included along with the underlying information or data that supports how the standard was used.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			<input checked="" type="checkbox"/>		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
a) The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
14) The submission includes descriptive information for the device, including the following:				<input type="checkbox"/>	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
c) A list and description of each device for which clearance is requested.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
15) Device is intended to be marketed with accessories and/or as part of a system.	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				<input type="checkbox"/>	

<p>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</p> <p>*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.</p>	Yes	No	N/A	Comment	*Page #
<p>a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status.</p> <p><i>Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]</p> <p><i>See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.</i></p>				<input type="checkbox"/>	
<p>a) Indications for Use</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>b) Technology, including technical specifications, features, materials, and principles of operation</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)</p>					
<p>18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
<p>a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>b) Labeling includes:</p> <ul style="list-style-type: none"> - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) <p>AND</p> <ul style="list-style-type: none"> - Includes adequate directions for use (see 21 CFR 801.5) <p>OR</p> <ul style="list-style-type: none"> - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D 	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
<p>19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
<p>20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.</p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. <small>Records processed under FOIA Request 2023-9460. Released by CDRH on 04-09-2024</small> *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) The submission addresses labeling recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per <u>21 CFR 809.10</u> .	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
E. Sterilization					
If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			<input type="checkbox"/>		
<input checked="" type="checkbox"/> Provided sterile, intended to be single-use					
<input type="checkbox"/> Requires processing during its use-life					
<input type="checkbox"/> Non-sterile when used (and no processing required)					
<input type="checkbox"/> Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
<input type="checkbox"/> Sterility status not needed for this device (e.g., software-only device)					
<input type="checkbox"/> Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. Please refer to the FDA guidance document " <u>Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling</u> ," available at <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling</u> , for additional information.					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				<input type="checkbox"/>	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
c) Identification of device, and/or accessories, if applicable, that are reusable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
24) If the device and/or accessories, if applicable, are provided sterile:				<input type="checkbox"/>	<input type="checkbox"/>
a) Sterilization method is stated for each device (including dose for radiation sterilization).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
d) Sterility Assurance Level (SAL) is stated.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
e) Submission includes description of packaging.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amoebocyte lysate [LAL]).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled " Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications " (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
i) If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.
 *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

Yes	No	N/A	Comment	*Page #
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F. Shelf Life

27) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	

G. Biocompatibility

<i>If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>			<input type="checkbox"/>		
Submission states that there: (one of the below must be checked)		<input type="checkbox"/>		<input type="checkbox"/>	
<input checked="" type="checkbox"/> Are direct or indirect tissue-contacting components.					
<input type="checkbox"/> Are no direct or indirect tissue-contacting components.					
<input type="checkbox"/> Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
<input type="checkbox"/> Tissue contact information not needed for this device (e.g., software-only device)					
<input type="checkbox"/> Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
31) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. <small>Records processed under FOIA Request 2023-9460. Released by CDRH on 04-09-2024</small> *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled " Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,' available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and-testing-within-a-risk-management-process), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of " Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,' " methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled " Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' " provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	<input type="checkbox"/>		<input type="checkbox"/>	
H. Software					
Submission states that the device: (one of the below must be checked)		<input type="checkbox"/>		<input type="checkbox"/>	
<input type="checkbox"/> Does contain software/firmware					
<input checked="" type="checkbox"/> Does not contain software/firmware					
<input type="checkbox"/> Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
<input type="checkbox"/> Software/firmware information not needed for this device (e.g., surgical suture, condom)					
<input type="checkbox"/> Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: (one of the below must be checked)		<input type="checkbox"/>		<input type="checkbox"/>	
<input type="checkbox"/> Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
<input checked="" type="checkbox"/> Does not contain external interfaces as described above					
<input type="checkbox"/> Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
<input type="checkbox"/> Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
<input type="checkbox"/> Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <small>Questions contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118</small>					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Records processed under FOIA Request 2023-9460. Released by CDRH on 04-09-2024				
	Yes	No	N/A	Comment	*Page #

J. Electrical Safety and EMC

Electrical Safety Submission states that the device: <i>(one of the below must be checked)</i>		<input type="checkbox"/>		<input type="checkbox"/>	
<input type="checkbox"/> Does require electrical safety evaluation					
<input checked="" type="checkbox"/> Does not require electrical safety evaluation					
<input type="checkbox"/> Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
<input type="checkbox"/> Electrical safety information not needed for this device (e.g., surgical suture, condom)					
<input type="checkbox"/> Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

EMC Submission states that the device: <i>(one of the below must be checked)</i>		<input type="checkbox"/>		<input type="checkbox"/>	
<input type="checkbox"/> Does require EMC evaluation					
<input checked="" type="checkbox"/> Does not require EMC evaluation					
<input type="checkbox"/> Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
<input type="checkbox"/> EMC information not needed for this device (e.g., surgical suture, condom)					
<input type="checkbox"/> EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

K. Performance Data - General

If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			<input type="checkbox"/>		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket . If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices .	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
40) If literature is referenced in the submission, submission includes:			<input checked="" type="checkbox"/>		
41) For each completed animal study, the submission provides the following:			<input type="checkbox"/>	<input type="checkbox"/>	
a) Submission includes a study protocol which includes all elements as outlined in <u>21 CFR 58.120</u> .	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
b) Submission includes final study report which includes all elements outlined in <u>21 CFR 58.185</u> .	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (<u>21 CFR Part 58</u>), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
L. Performance Characteristics - In Vitro Diagnostic Devices Only (Also see <u>21 CFR 809.10(b)(12)</u>)					
Submission states that the device: (one of the below must be checked)				<input type="checkbox"/>	
<input type="checkbox"/> is an in vitro diagnostic device.					
<input checked="" type="checkbox"/> is not an in vitro diagnostic device.					
<i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>					

Digital Signature Concurrence Table

Reviewer Sign-Off

**Ramesh C.
Panguluri -S** Digitally signed by
Ramesh C. Panguluri -S
Date: 2020.02.07
09:40:33 -05'00'

Management Sign-Off
(digital signature
optional)*



* Management review of checklist and concurrence with decision required.

SECTION 15: SUBSTANTIAL EQUIVALENCE

The new size options are a line extension to the existing cleared QuikClot Control+® Hemostatic Dressing product line. The subject devices are identical to the predicate in terms of materials of construction, hemostatic agent used, formulation, indications for use, intended uses, mode of operation, and scientific technological characteristics. All materials used to manufacture the subject device meet the biocompatibility requirements for the applicable tests. The new size options will be provided sterile utilizing existing validated sterilization parameters and packaging systems. Refer to **Table 6** below for the substantial equivalence chart.

Table 6: Substantial Equivalence Chart

Parameter	Subject Device QuikClot Control+® Hemostatic Dressing – Line Extension	Predicate Device QuikClot Control+® Hemostatic Dressing (DEN160012)	Reference Device QuikClot Control+® Hemostatic Dressing (K140757)
Indications for Use / Intended Use	QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.	QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.	QuikClot Control+® Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.
Materials of Construction	Gauze Substrate, Kaolin (hemostatic agent), and (b)(4) (binder)	Gauze Substrate, Kaolin (hemostatic agent), and (b)(4) (binder)	Gauze Substrate, Kaolin (hemostatic agent), and (b)(4) (binder)
Sizes	Various sizes including but not limited to 1" x 1", 3 ply; 4" x 2", 6 ply or 10 ply; 4" x 6", 6 ply or 10 ply; 4" x 8", 6 -10 plies; 4" x 12", 9 ply	Various sizes including but not limited to, 2"x 2", 5"x 5", 12" x 12", 3" x 4 yds, and 4" x 4" yds	Various sizes ranging from 1" x 1" x 1 ply to 4" x 12ft x 2 ply
Prescription Use or Over-the-Counter (OTC)	Prescription Use	Prescription Use	Prescription Use
Patient Contact Time	Up to 48 hours	Up to 48 hours	Up to 48 hours
How Supplied	Sterile	Sterile	Sterile

Parameter	Subject Device QuikClot Control+® Hemostatic Dressing – Line Extension	Predicate Device QuikClot Control+® Hemostatic Dressing (DEN160012)	Reference Device QuikClot Control+® Hemostatic Dressing (K140757)
Sterilization Method	Gamma	Gamma	Gamma
Single Use / Reusable	Single-use	Single-use	Single-use
Packaging	Peelable foil pouch	Peelable foil pouch	Peelable foil pouch

In conclusion, the additional product configurations do not raise new types of questions of safety and effectiveness and are substantially equivalent to the predicate device.

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K200167

Device Name
QuickClot Control+® Hemostatic Dressing

Indications for Use (Describe)
QuickClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

CONTROL+[®]

HEMOSTATIC DRESSING

Description

QuikClot Control+[®] consists of a white to off-white to yellow, sterile, 6-ply, 4 in x 8 in, X-Ray detectable hemostatic dressing is packaged for aseptic removal.

Indications

QuikClot Control+[®] is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Contraindications

- Do not leave QuikClot Control+ in place for more than 48 hours.
- QuikClot Control+ is not indicated for intraluminal vascular use.

Warnings

- Adhesion formation associated with QuikClot Control+ dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesions elicited by QuikClot Control+ dressing are equivalent to those caused by control materials.
- QuikClot Control+ dressing is not absorbable and must be removed from the wound prior to wound closure.

Precautions

- If bleeding persists, additional product may be applied to the wound.

Directions for Use

1. Verify the expiration date on the package labels prior to using the product.
Open package and remove QuikClot Control+ dressing.
2. Apply QuikClot Control+ dressing to the wound and apply compression until bleeding is controlled. More than one dressing may be required.
NOTE: If needed, additional gauze or a pressure dressing may be applied to maintain compression. The time for formation of a stable clot may vary depending on several patient factors.
3. Remove the dressing and repair the wound, if necessary. If the dressing is adhered to the wound, hydrate with sterile saline to aid in removal.
4. Copiously irrigate the QuikClot Control+ dressing application sites and completely suction irrigation fluid prior to wound closure.

Storage Conditions

Keep dry. Keep away from heat, including storage in direct sunlight or in direct contact with heat sources.

Sterility and Expiration

Product is sterilized by exposure to gamma radiation and is intended for single use only. Do not attempt to resterilize the device by any means. Do not use if the sterile pouch is damaged or opened. Do not use the device after the expiration date listed on the package.

QuikClot
CONTROL⁺
HEMOSTATIC
DRESSING

**Instructions
for Use**

**4 in x 8 in 6-Ply
Dressing**

M Manufactured by:
Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492 USA
Tel: 1-877-750-0504, +1-203-294-0000
Fax: 1-800-343-8656, +1-203-303-7216
QuikClotControlPlus.com
Patents: Z-Medica.com/patents.aspx
© 2017 Z-Medica, LLC
All rights reserved.
Made in the USA
101714-01 Rev C 8/1/18

h4000

Rx ONLY



Food and Drug Administration
 CDRH/OPEQ/OHTIV/DHTIVB
 WO66 RM4604
 10903 New Hampshire Ave
 Silver Spring, MD 20993-0002
 301-796-6303

Premarket Notification 510(k) Review

Post-Review Reminders

- Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: March 24, 2020			
Reviewer: Ramesh K Panguluri			
Subject: Traditional 510(k)# K200167			
Applicant: Z-Medica, LLC		Device Trade Name: QuikClot Control+	
Contact Name: Soraya King		Contact Title: Director, Regulatory Affairs	
Correspondent Firm: Z-Medica, LLC		Phone: (203) 980-6067 Email: sking@z-medica.com	
Received Date: January 23, 2020		Due Date: April 23, 2020	
Pro Code(s): POD Class: II Reg #: 878.4454		Reg Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
DEN160012	POD	D2 Dressing	Z-medica, LLC
K140757	FRO	D2 Hemostantic Dressing	Z-medica, LLC

(b)(5)

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Digital Signature Concurrence Table (Doc ID: 04500.14.00)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Ramesh C.
Panguluri -S

Digitally signed by Ramesh C.
Panguluri -S
Date: 2020.03.24 15:25:20
-04'00'

From: Mason, Tiffani * [Tiffani.Mason@fda.hhs.gov]
Sent: 3/27/2020 4:50:13 PM
To: sking@z-medica.com
Subject: K200167/S001 Acknowledgement Notification
Attachments: K200167.S001-Letter.pdf

Tiffani R. Mason
Tiffani.Mason@fda.hhs.gov
Record Management Specialist 1 DCC 510K



Acknowledgment Letter

3/27/2020

Soraya King, Director, Regulatory Affairs
Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492
UNITED STATES

Dear Soraya King:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K200167/S001
Received: 3/27/2020
Applicant: Z-Medica, LLC
Device: QuikClot Control+

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

Z-MEDICA

It's QuikClot Or It's Not

21 January 2020

510(k) Document Mail Center (W066-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Cynthia Chang, Ph.D., Director, Division of Health Technology 4B (Infection Control & Plastic Surgery Devices).

Re: Traditional 510(k) Premarket Notification for Z-Medica, LLC's QuikClot Control+® Hemostatic Dressing – Line Extension for Additional Size Offering

Dear Dr. Chang,

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, Z-Medica, LLC is submitting this Traditional 510(k) Premarket Notification, prior to commercial distribution, for clearance of additional size options of our QuikClot Control+® Hemostatic Dressing (DEN160012 wherein the device was referred to as D2 Dressing). The currently cleared indications for use and intended uses, DEN160012, will remain the same. The new size options do not represent a change in technological characteristics, principles of operation, safety, or effectiveness of the device.

(b)(4)

Z-Medica, LLC is FDA registered as a Small Business under decision number SBD208319. Therefore, in accordance with Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Z-Medica, LLC has submitted the required application fee of **(b)(4)** (FY 2020 MDUFA User Fees). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

As per FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s (13 September 2019)*, the principal factors about the design and use of the additional QuikClot Control+® size offering comply with the following:

Page 1 of 2



Z-MEDICA

It's QuikClot Or It's Not

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

^AA device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Z-Medica, LLC is providing one (1) ecopy of this submission with this signed cover letter as per the *eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff* dated 16 December 2019. The signed cover letter is the only paper document included with this submission. All supporting information, to include an ecopy of the signed cover letter, are included in the USB drive.

This submission contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.

The official contact person for this submission is the undersigned. Thank you in advance for the review of this submission.

Respectfully submitting,

(b)(6)

Soraya King
 Director, Regulatory Affairs
 Z-Medica, LLC
 Cell: **(b)(6)**
 Office: 203-774-7922



(b)(4)

Sponsor:

(b)(4)

Z-Medica, LLC

4 Fairfield Blvd.

Wallingford, CT 06492

Attachment 3: Irritation Test, Page 1 of 28

ISO Intracutaneous Irritation Test (GLP – 2 Extracts)

Test Article: Sample ID: QuikClot Control + Hemostatic Dressing 12 in x 12 in 3-ply Dressing.

Lot #: (b)(4)

Purchase Order:

Study Number:

Study Received Date:

Testing Facility:

Deviations: None

(b)(4)

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4)

(b)(4)

05 NOV 2018

Date

(b)(4)

(b)(4)

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(b)(4)

Z-MEDICA		Report for Sterilization Validation (b)(4) for QuikClot and QuikClot Control+ Hemostatic Dressings	
Document No.:	(b)(4)	Revision Date:	(b)(4)
Prepared by:		Title:	(b)(4)
Sections Changed in the Current Revision			
(b)(4)			

(b)(4)

(b)(4)

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Attachment 1

Validation Protocol

(b)(4)

(b)(4)

Gamma Sterilization Validation Protocol

(b)(4)

Method for Z-Medica Products

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 8: Sterilization Validation Confirmation, Page 17 of 48

Attachment 2

Validation Report

(b)(4)

(b)(4)

(b)(4)

Gamma Sterilization Validation Final Report
(b)(4) Method for Z-Medica Products

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 8: Sterilization Validation Confirmation, Page 23 of 48

Attachment 3

Bioburden Reports

(b)(4)

(b)(4)

BIOBURDEN TEST REPORT

CLIENT: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

TEST#: **(b)(4)**

DATE: 11/11/19

REPORT TO: **(b)(4)**

SAMPLE DESCRIPTION:

QuikClot Control - Hemostatic Dressing **(b)(4)**
(b)(4)

TEST REQUESTED:

(b)(4)

REFERENCE DOCUMENT:

ANSI/AAMI/ISO 11737-1:2018 Sterilization of health care products -- Microbiological methods -- Part 1: Determination of the population of microorganisms on product.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 8: Sterilization Validation Confirmation, Page 29 of 48

Attachment 4

Bacteriostasis &

Fungistasis Reports

(b)(4)

(b)(4)

BACTERIOSTASIS & FUNGISTASIS TEST REPORT

CLIENT: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

TEST#: **(b)(4)**

DATE: 12/19/19

REPORT TO: Joe Azary

SAMPLE DESCRIPTION:

(b)(4)

TEST REQUESTED:

Suitability Test (Bacteriostasis & Fungistasis), Product Immersion

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 8: Sterilization Validation Confirmation, Page 35 of 48

Attachment 5

Sterility Test Reports & Dose Verification Data

(b)(4)

(b)(4)

STERILITY TEST REPORT

CLIENT: Z-Medica
4 Fairfield Boulevard
Wallingford, CT 06492

TEST#: **(b)(4)**

DATE: 12/17/19

REPORT TO: **(b)(4)**

PRODUCT:
(10)

(b)(4)

TEST REQUESTED:
Sterility Test (Low Dose Verification)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 8: Sterilization Validation Confirmation, Page 43 of 48

Attachment 6

Bioburden Recovery Report

(b)(4)

(b)(4)

BIOBURDEN RECOVERY TEST

CLIENT: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

TEST#: **(b)(4)**

DATE: 11/13/19

REPORT TO: **(b)(4)**

SAMPLE DESCRIPTION:

(b)(4)

TEST REQUESTED:

Bioburden Recovery **(b)(4)**

(b)(4)

(b)(4)

(b)(4)

(b)(4)

SECTION 7: CLASS III SUMMARY AND CERTIFICATION

This section does not apply as the QuikClot Control+® Hemostatic Dressing is not a Class III device.

Through the De Novo classification request (DEN160012), this device has been designated as Class II under new regulation number 21 CFR §878.445 and product code POD.

SECTION 5: 510(k) SUMMARY (K200167)

510(k) Number:

Submitter: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

Contact Person: Soraya King, Director Regulatory Affairs

Preparation Date: 21 January 2020

Trade/Device Name: QuikClot Control+® Hemostatic Dressing

Regulatory Description and Classification: Common Name: Temporary, Internal Use Hemostatic Wound Dressing
Generic Name: Non-absorbable, hemostatic gauze for temporary internal use.
Device Classification: Class II
Regulation Number: 21 CFR §878.4454
Product Code: POD

Predicate Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (DEN160012, cleared as D2 Dressing)

Reference Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (K140757, cleared as D2 Dressing)

Indications for Use: QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Device Description: QuikClot Control+® Hemostatic Dressing is a prescription use non-absorbable device containing kaolin (hemostatic agent) bound to gauze. The hemostatic dressings are x-ray detectable and are provided as a single-use sterile device available in various sizes. The device is available in single or multipacks.

Special Controls: Device complies with the requirements as per 21 CFR 878.4454 for non-absorbable, hemostatic gauze for temporary internal use.

Mechanism of Action: The QuikClot Control+® Hemostatic Dressings are packed into or on the wound and pressure is applied. Pressure is maintained until the bleeding is controlled and may be left in place up to 48 hours. More

than one QuikClot Control+® hemostatic dressing can be used. Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression.

Summary of Technological Characteristics:

The fundamental scientific and technological characteristics of the modified device are identical to the predicate (DEN160012). The key characteristics are as follows:

- Mechanism of Action
- Materials of Construction
- Formulation
- Packaging Materials
- Sterilization Method
- Performance Specifications
- Indications/Intended Uses

Performance Testing:

The QuikClot Control+® Hemostatic Dressing complies with the special controls identified in 21 CFR 878.4454. All of the size offerings are the manufactured with the same exact materials and formulation. The device meets the following performance specifications:

- Biocompatibility as per ISO 10993-1 for a device with prolonged patient contact duration (>24 hours to 30 days) for external communicating device with tissue/bone/dentin contact.
 - Cytotoxicity (L929 Neutral Red Uptake Method)
 - Irritation (Intracutaneous Injection)
 - Sensitization (Guinea Pig Maximization Sensitization Test)
 - Systemic Injection (Intravenous Injection and Intraperitoneal Injection – Acute Systemic Toxicity)
 - Implantation (Rabbit Implantation Tests – Tissue, Muscle, and Bone)
 - 4-week implantation study in subcutaneous tissue
 - 1-week implantation study in muscle
 - 4-week implantation study in muscle
 - 4-week implantation study in bone
 - 8-week implantation study in bone
 - Genotoxicity
 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
 - Chromosomal Aberration Study in Mammalian Cells
 - Peripheral Blood Micronucleus Study in Mouse
 - Additional Supporting Tests
 - Carcinogenicity (Clonal Transformation Assay using SHE Cells for 7-days)
 - Repeat Exposure System Toxicity for Kaolin (6-month animal survival study, custom test)
 - Systemic Intravenous Injection for Kaolin Extract
 - Systemic Intraperitoneal Injection for Kaolin Extract

▪ Pyrogen Test

- X-Ray Detectable Material - meets required specifications.
- Bench – the device meets the required specifications and acceptance criteria for tensile strength, elongation, clotting, and kaolin release.
- Preclinical Animal Study – Three GLP large animal (swine), to include a survival model, and one non-GLP study demonstrated the safety and effectiveness of QuikClot Control+. The studies included assessments such as hemostasis. In addition to hemostasis assessments, the animal survival study also conducted evaluations for blood chemistry (hematology, serum, coagulation), and macroscopic and microscopic tissue/organ examinations (adhesion, thromboembolism, kaolin migration). The cumulative animal study results support the substantial equivalence of the device.
- Stability – testing supports a 39-month expiration date.

Conclusion

The subject devices are identical to the predicate in terms of materials of construction, hemostatic agent used, mode of operation, scientific technological characteristics, indications for use and intended uses. Same as the predicate device, the new size options will be provided sterile utilizing existing validated packaging systems. The additional size offerings do not raise new types of questions of safety and effectiveness and is substantially equivalent to the predicate device.

Z-MEDICA®

LETTER TO FILE

Title	Engineering Analysis: Additional QuikClot Control+ Configurations	Date	January 20, 2020
Prepared by	(b)(4)		
Summary	The purpose of this analysis is to confirm no additional testing is needed for the new proposed configurations of QuikClot Control+.		

Scope

This engineering analysis shows that previously cleared configurations of QuikClot Control+ provide justification to new proposed configurations of QuikClot Control+ for the following device parameters: materials, biocompatibility & biocompatibility testing, sterilization method & sterilization validation, packaging system, shelf life & shelf life testing. This analysis is limited to the QuikClot Control+ configurations discussed in the Table below. The new configurations include 1" x 1", 3 ply; 4"x2", 6 ply; 4" x 2", 10 ply; 4"x6", 6 ply; 4"x6", 10 ply; 4" x 8", 6 ply; 4" x 8", 7 ply; 4" x 8", 8 ply; 4" x 8", 9 ply; 4" x 8", 10 ply; and 4" x 12", 9 ply.

(b)(4)

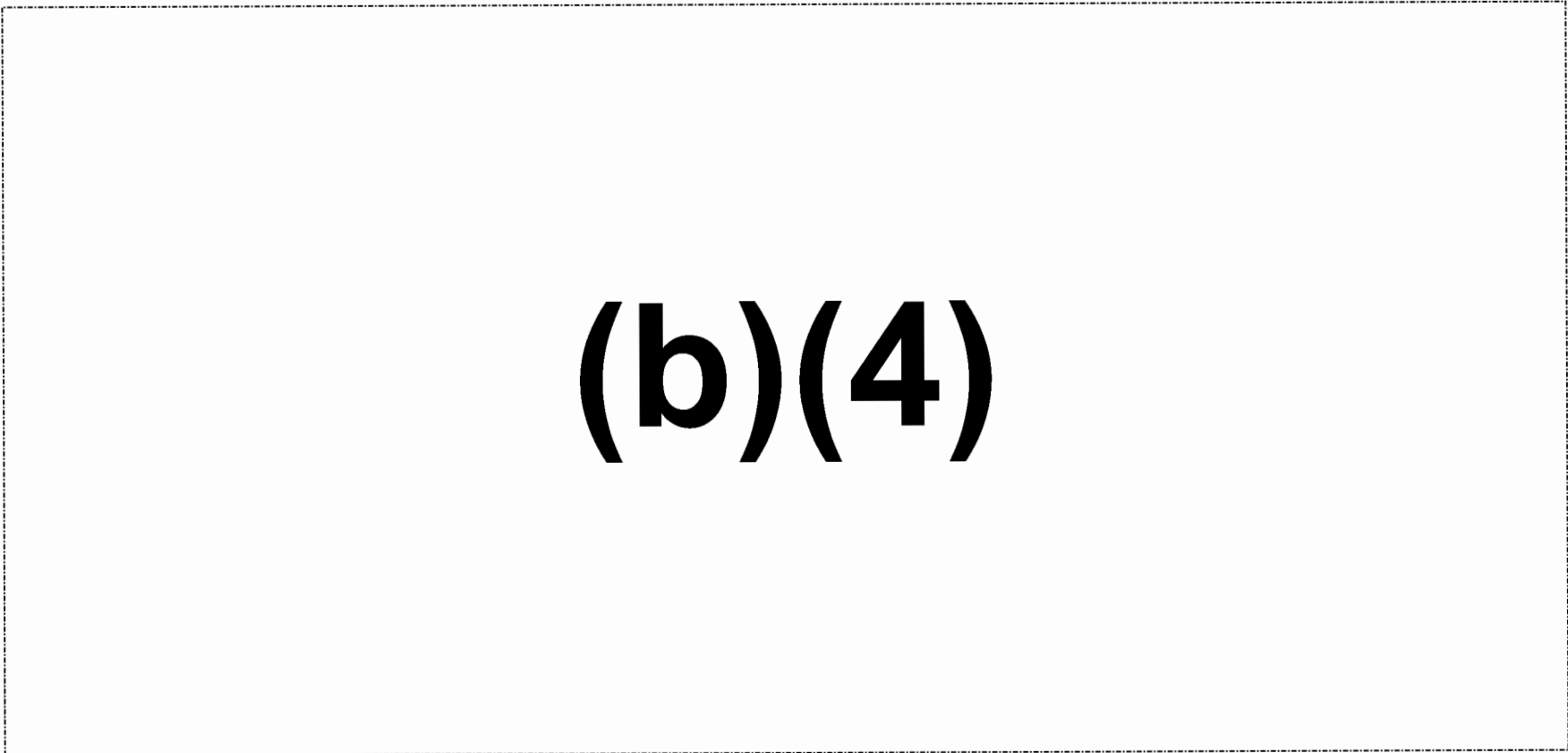
PROPRIETARY & CONFIDENTIAL

This document and the information herein are the property of Z-Medica LLC, and neither may be used for any purpose, nor disclosed to any party, without the written consent of Z-Medica LLC.

Z-MEDICA [®]	Date:	Author:
	January 20, 2020	Antoine Kaeslin
Engineering Analysis: Additional QuikClot Control+ Configurations		

Attachment 7: Engineering Analysis for the Additional QuikClot Control+ Configurations

Analysis



(b)(4)

PROPRIETARY & CONFIDENTIAL

This document and the information herein are the property of Z-Medica LLC, and neither may be used for any purpose, nor disclosed to any party, without the written consent of Z-Medica LLC.

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Build Correspondence

Convert to PDF

Z-Medica, LLC
Soraya King
Director, Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K200167

Trade/Device Name: QuikClot Control+
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: March 26, 2020
Received: March 27, 2020

Dear Soraya King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Z-MEDICA

It's QuikClot Or It's Not

23 January 2020

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Cynthia Chang, Ph.D., Director, Division of Health Technology 4B (Infection Control & Plastic Surgery Devices).

Re: **510k #K200167 – eCopy Replacement**
Traditional 510(k) Premarket Notification for Z-Medica, LLC's QuikClot Control+® Hemostatic Dressing – Line Extension for Additional Size Offering

Dear Dr. Chang,

As per the eCopy Hold Notification (dated 23 January 2020), Z-Medica is resubmitting the 510k with the required corrections. The format of the eCopy was updated to separate Sections 10 – 15 so that the title descriptors do not exceed the 125 character requirement. As such, the Table of Contents has also been revised to reflect the updates. All documents are in pdf. format.

Z-Medica, LLC is providing one (1) ecopy replacement of the entire submission with this signed ecopy replacement cover letter. This signed ecopy replacement cover letter is the only paper document included with this resubmission. All supporting information, to include a copy of the signed ecopy replacement cover letter, are included in the USB drive. The copy of this cover letter is provided as **Attachment 12** and a copy of the FDA eCopy Hold Notification is included as **Attachment 13**.

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, Z-Medica, LLC is submitting this Traditional 510(k) Premarket Notification, prior to commercial distribution, for clearance of additional size options of our QuikClot Control+® Hemostatic Dressing (DEN160012 wherein the device was referred to as D2 Dressing). The currently cleared indications for use and intended uses, DEN160012, will remain the same. The new size options do not represent a change in technological characteristics, principles of operation, safety, or effectiveness of the device.

Page 1 of 3



(b)(4)

Z-Medica, LLC is FDA registered as a Small Business under decision number SBD208319. Therefore, in accordance with Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Z-Medica, LLC has submitted the required application fee of **(b)(4)** (FY 2020 MDUFA User Fees). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

As per FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (13 September 2019), the principal factors about the design and use of the additional QuikClot Control+® size offering comply with the following:

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

^AA device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

This submission contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.



Z-MEDICA

It's QuikClot Or It's Not

The official contact person for this submission is the undersigned. Thank you in advance for the review of this submission.

Respectfully submitting,

(b)(6)

Soraya King
Director, Regulatory Affairs
Z-Medica, LLC
Cell: **(b)(6)**
Office: 203-774-7922





K200167
Z-Medica, LLC
Trade/Device Name: QuikClot Control+
Contact Name: Soraya King

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K200167 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K200167 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at <https://www.fda.gov/media/83522/download> for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (<https://www.fda.gov/media/71735/download>) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

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FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at <https://www.fda.gov/media/114034/download>.

Least Burdensome (LB) Flag

The LB flag is an approach to allow 510(k) submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.

- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact 510K_Program@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistance Director. You should also copy 510K_Program@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact 510K_Program@fda.hhs.gov.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Attachment 1: DEN160012 De Novo Designation Summary, Page 1 of 4

Z-Medica, LLC
Ms. Sheila K. Wallin
Vice President of Clinical and U.S. Regulatory Affairs
4 Fairfield Boulevard
Wallingford, CT 06492 US

September 1, 2017

Re: DEN160012
D2 Dressing
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 878.4454
Regulatory Classification: Class II
Product Code: POD
Dated: March 16, 2016
Received: March 16, 2016

Dear Ms. Wallin,

This letter corrects our classification order dated June 30, 2017.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the D2 Dressing, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

D2 Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the D2 Dressing and substantially equivalent devices of this generic type, into class II under the generic name, non-absorbable, hemostatic gauze for temporary internal use.

FDA identifies this generic type of device as:

Non-absorbable, hemostatic gauze for temporary internal use. A non-absorbable, hemostatic gauze for temporary internal use is a prescription device intended to be placed temporarily for control of severely bleeding wounds such as surgical wounds and traumatic injuries. The gauze is coated or impregnated with a hemostatic material which may enhance hemostasis by physical means. The device is intended to be removed once the patient is stabilized.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012.

This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On March 16, 2016, FDA received your De Novo requesting classification of the D2 Dressing into class II. The De Novo request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the D2 Dressing into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the De Novo request which included biocompatibility, performance bench, and performance animal testing on the D2 Dressing along with clinical data on a previous formulation of the device (D1 Dressing), FDA has determined that the D2 Dressing, indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding as well as control of severely bleeding wounds such as surgical wounds and traumatic injuries, can be classified into class II with the establishment of special controls. FDA believes that special controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table I.

Table 1: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Infection	Shelf Life Testing Sterilization Validation Labeling
Bleeding <ul style="list-style-type: none"> • Failure of Hemostasis • Recurrence of Bleeding 	Animal Performance Testing Technological Specifications
Vascular Obstruction <ul style="list-style-type: none"> • Ischemia • Emboli Formation 	Animal Performance Testing Labeling
Adhesion Formation	Animal Performance Testing Labeling
Adverse Tissue Reaction	Animal Performance Testing Biocompatibility Evaluation
Device Retained in Body Leading to Re-Operation	Animal Performance Testing Non-Clinical Performance Testing Labeling

In combination with the general controls of the FD&C Act, the non-absorbable, hemostatic gauze for temporary internal use is subject to the following special controls:

1. Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Specifically testing must:
 - a) Demonstrate that the device is able to achieve hemostasis;
 - b) Demonstrate that the device can be radiographically detected; and
 - c) Assess pertinent safety endpoints including vascular obstruction and adhesion formation.
2. The device must be demonstrated to be biocompatible.
3. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following tests must be performed:
 - a) *In vitro* clot assessment;
 - b) Particulate release testing;
 - c) Physical characterization, including swelling percent and particulate size;
 - d) Chemical characterization;
 - e) Radiopacity testing; and
 - f) Mechanical integrity testing, including tensile strength and tear strength.
4. Performance data must demonstrate the sterility of the device.
5. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
6. Labeling must include the following:
 - a) Instructions for use, including an instruction to remove all visible device components by irrigation;
 - b) The maximum amount of time the device may be left within the body;
 - c) A shelf life;
 - d) A contraindication for intravascular use of the device; and
 - e) A warning regarding the potential for adhesion formation.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Brendan J. Casey, Ph.D. at 301-796-9607.

Sincerely,


Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Science and Engineering Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Attachment 2: 510K #K140757 SE Letter, Page 1 of 3

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- W066-G609
Silver Spring, MD 20993-0002

July 17, 2014

Z-Medica, LLC
Ms. Sheila K. Wallin
Vice President of Clinical & U.S. Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K140757

Trade/Device Name: D2 Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 29, 2014
Received: May 1, 2014

Dear Ms. Wallin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Sheila K. Wallin

Attachment 2: 510K #K140757 SE Letter, Page 2 of 3

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K140757

Device Name

D2 Hemostatic Dressing

Indications for Use (Describe)

D2 Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Jiyoung Dang -S

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

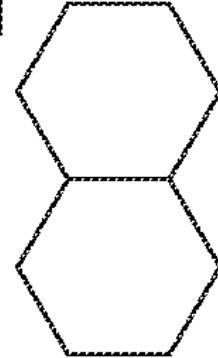
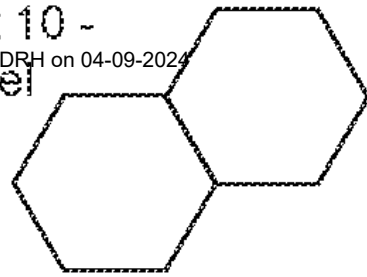
QuikClot


CONTROL⁺

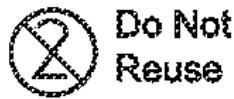
HEMOSTATIC DRESSING

8 in x 4 in (20.3 cm x 10.2 cm)

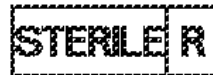
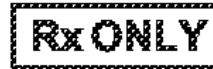
One (1) 6-Ply Dressing



 **Manufactured by:**
Z-Medica, LLC
4 Fairfield Boulevard,
Wallingford, CT 06492 USA
Tel: 1-877-750-0504, +1-203-294-0000
Fax: 1-800-343-8656, +1-203-303-7216
QuikClotControlPlus.com
Patents: Z-Medica.com/patents.aspx
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101XXX-01 Rev A



**Do Not
Reuse**



**Read
Instructions
For Use**

REF XXXX

LOT XXXXX-XXX


 YYYY-DD-MM

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eCopy Hold Letter

1/23/2020

Soraya King, Director, Regulatory Affairs
Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492
UNITED STATES

Dear Soraya King:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K200167
Received: 1/23/2020
Applicant: Z-Medica, LLC
Device: QuikClot Control+

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, “eCopy Program for Medical Device Submissions” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>.

Please write the specific submission number identified above **AND** “Replacement eCopy” directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You should provide the complete content for the document, not just the corrected files or folders, in your replacement eCopy. **When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.**

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

Attachment

Attachment

Attachment for Submission Number(s):

K200167

(b)(4)

From: [Panguluri Ramesh](#)
To: [King, Soraya](#)
Cc: [Panguluri Ramesh](#)
Subject: K200167 is on Hold Pending Your Response
Date: Tuesday, March 24, 2020 10:49:11 PM
Attachments: [K200167.AdditionalInformation.AINN.pdf](#)

March 24, 2020

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Panguluri Ramesh.

*** This is a system-generated email notification ***



K200167
Z-Medica, LLC
Trade/Device Name: QuikClot Control+
Contact Name: Soraya King

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K200167 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K200167 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at <https://www.fda.gov/media/83522/download> for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

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This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (<https://www.fda.gov/media/71735/download>) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at <https://www.fda.gov/media/114034/download>.

Least Burdensome (LB) Flag

The LB flag is an approach to allow 510(k) submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.

- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
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- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

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K200167
Z-Medica, LLC
Trade/Device Name: QuikClot Control+
Contact Name: Soraya King

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K200167 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K200167 to:

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Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

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From: Zhao, Liqun
To: Panguluri, Ramesh K
Cc: Qian, Bifeng; Claverie, Elizabeth F; Murray III, Clarence
Subject: K200167/S001 Biocompatibility Consult
Date: Wednesday, April 08, 2020 12:34:38 PM

Hi Kapil,

The information provided in the K200167/S001 is sufficient to address the (b)(4) raised in AINN letter, I do not have outstanding concerns. Please let me know if you have any questions.

AINN Deficiency:

(b)(4)

Sponsor's Response:

(b)(4)

Thanks,
Liqun

Z-MEDICA

It's QuikClot Or It's Not

FDA/CDRH/DCC

MAR 27 2020

RECEIVED

26 March 2020

U.S. Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K200167/SW1

Attention: Ramesh Kapil Panguluri, Ph.D., Lead Reviewer, Office of Surgical and Infection Control Devices (OHT4).

Re: 510(k) #K200167 – QuikClot Control+® Hemostatic Dressing Line Extension for Additional Size Offering, Z-Medica LCC's Response to FDA's Additional Information Request.

Dear Dr. Panguluri,

Enclosed please find the response to FDA's additional information email request dated 24 March 2020 for Z-Medica's 501(k) #K200167. We believe the responses address all of the additional information and clarification requested. A copy of the request is included with this response. The responses are structured where the FDA's questions are listed first and italicized followed by Z-Medica's clarification.

Z-Medica, LLC is providing one (1) ecopy of this submission with this signed cover letter as per the *eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff* dated 16 December 2019. The signed cover letter is the only paper document included with this submission. All supporting information, to include an ecopy of the signed cover letter, are included in the USB drive. The additional information and clarification contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.

Thank you in advance for the review of this submission.

Respectfully submitting

(b)(6)

Soraya King
Director, Regulatory Affairs
Z-Medica, LLC
Cell: (b)(6)
Office: 203-774-7922



93



Build Correspondence

Convert to PDF

K200167
Z-Medica, LLC
Trade/Device Name: QuikClot Control+
Contact Name: Soraya King

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

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Document Control Center - WO66-G609
10903 New Hampshire Avenue
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MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

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**U.S. FOOD & DRUG
ADMINISTRATION**

April 23, 2020

Z-Medica, LLC
Soraya King
Director, Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K200167

Trade/Device Name: QuikClot Control+
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: March 26, 2020
Received: March 27, 2020

Dear Soraya King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.

Acting Assistant Director

DHT4B: Division of Infection Control
and Plastic Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K200167

Device Name
QuickClot Control+® Hemostatic Dressing

Indications for Use (Describe)
QuickClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

SECTION 5: 510(k) SUMMARY (K200167)

510(k) Number:

Submitter: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

Contact Person: Soraya King, Director Regulatory Affairs

Preparation Date: 21 January 2020

Trade/Device Name: QuikClot Control+® Hemostatic Dressing

Regulatory Description and Classification: Common Name: Temporary, Internal Use Hemostatic Wound Dressing
Generic Name: Non-absorbable, hemostatic gauze for temporary internal use.
Device Classification: Class II
Regulation Number: 21 CFR §878.4454
Product Code: POD

Predicate Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (DEN160012, cleared as D2 Dressing)

Reference Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (K140757, cleared as D2 Dressing)

Indications for Use: QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Device Description: QuikClot Control+® Hemostatic Dressing is a prescription use non-absorbable device containing kaolin (hemostatic agent) bound to gauze. The hemostatic dressings are x-ray detectable and are provided as a single-use sterile device available in various sizes. The device is available in single or multipacks.

Special Controls: Device complies with the requirements as per 21 CFR 878.4454 for non-absorbable, hemostatic gauze for temporary internal use.

Mechanism of Action: The QuikClot Control+® Hemostatic Dressings are packed into or on the wound and pressure is applied. Pressure is maintained until the bleeding is controlled and may be left in place up to 48 hours. More

than one QuikClot Control+® hemostatic dressing can be used. Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression.

Summary of Technological Characteristics:

The fundamental scientific and technological characteristics of the modified device are identical to the predicate (DEN160012). The key characteristics are as follows:

- Mechanism of Action
- Materials of Construction
- Formulation
- Packaging Materials
- Sterilization Method
- Performance Specifications
- Indications/Intended Uses

Performance Testing:

The QuikClot Control+® Hemostatic Dressing complies with the special controls identified in 21 CFR 878.4454. All of the size offerings are the manufactured with the same exact materials and formulation. The device meets the following performance specifications:

- Biocompatibility as per ISO 10993-1 for a device with prolonged patient contact duration (>24 hours to 30 days) for external communicating device with tissue/bone/dentin contact.
 - Cytotoxicity (L929 Neutral Red Uptake Method)
 - Irritation (Intracutaneous Injection)
 - Sensitization (Guinea Pig Maximization Sensitization Test)
 - Systemic Injection (Intravenous Injection and Intraperitoneal Injection – Acute Systemic Toxicity)
 - Implantation (Rabbit Implantation Tests – Tissue, Muscle, and Bone)
 - 4-week implantation study in subcutaneous tissue
 - 1-week implantation study in muscle
 - 4-week implantation study in muscle
 - 4-week implantation study in bone
 - 8-week implantation study in bone
 - Genotoxicity
 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
 - Chromosomal Aberration Study in Mammalian Cells
 - Peripheral Blood Micronucleus Study in Mouse
 - Additional Supporting Tests
 - Carcinogenicity (Clonal Transformation Assay using SHE Cells for 7-days)
 - Repeat Exposure System Toxicity for Kaolin (6-month animal survival study, custom test)
 - Systemic Intravenous Injection for Kaolin Extract
 - Systemic Intraperitoneal Injection for Kaolin Extract

▪ Pyrogen Test

- X-Ray Detectable Material - meets required specifications.
- Bench – the device meets the required specifications and acceptance criteria for tensile strength, elongation, clotting, and kaolin release.
- Preclinical Animal Study – Three GLP large animal (swine), to include a survival model, and one non-GLP study demonstrated the safety and effectiveness of QuikClot Control+. The studies included assessments such as hemostasis. In addition to hemostasis assessments, the animal survival study also conducted evaluations for blood chemistry (hematology, serum, coagulation), and macroscopic and microscopic tissue/organ examinations (adhesion, thromboembolism, kaolin migration). The cumulative animal study results support the substantial equivalence of the device.
- Stability – testing supports a 39-month expiration date.

Conclusion

The subject devices are identical to the predicate in terms of materials of construction, hemostatic agent used, mode of operation, scientific technological characteristics, indications for use and intended uses. Same as the predicate device, the new size options will be provided sterile utilizing existing validated packaging systems. The additional size offerings do not raise new types of questions of safety and effectiveness and is substantially equivalent to the predicate device.

510(k) Summary

Z-Medica, LLC QuikClot Control+® Hemostatic Dressing – Line Extension

SECTION 5: 510(k) SUMMARY

510(k) Number:

Submitter: Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

Contact Person: Soraya King, Director Regulatory Affairs

Preparation Date: 21 January 2020

Trade/Device Name: QuikClot Control+® Hemostatic Dressing

Regulatory Description and Classification: Common Name: Temporary, Internal Use Hemostatic Wound Dressing
Generic Name: Non-absorbable, hemostatic gauze for temporary internal use.
Device Classification: Class II
Regulation Number: 21 CFR §878.4454
Product Code: POD

Predicate Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (DEN160012, cleared as D2 Dressing)

Reference Device: Z-Medica, LLC QuikClot Control+® Hemostatic Dressing (K140757, cleared as D2 Dressing)

Indications for Use: QuikClot Control+® Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Device Description: QuikClot Control+® Hemostatic Dressing is a prescription use non-absorbable device containing kaolin (hemostatic agent) bound to gauze. The hemostatic dressings are x-ray detectable and are provided as a single-use sterile device available in various sizes. The device is available in single or multipacks.

Special Controls: Device complies with the requirements as per 21 CFR 878.4454 for non-absorbable, hemostatic gauze for temporary internal use.

Mechanism of Action: The QuikClot Control+® Hemostatic Dressings are packed into or on the wound and pressure is applied. Pressure is maintained until the bleeding is controlled and may be left in place up to 48 hours. More

510(k) Summary

Z-Medica, LLC QuikClot Control+® Hemostatic Dressing – Line Extension

than one QuikClot Control+® hemostatic dressing can be used. Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression.

Summary of Technological Characteristics:

The fundamental scientific and technological characteristics of the modified device are identical to the predicate (DEN160012). The key characteristics are as follows:

- Mechanism of Action
- Materials of Construction
- Formulation
- Packaging Materials
- Sterilization Method
- Performance Specifications
- Indications/Intended Uses

Performance Testing:

The QuikClot Control+® Hemostatic Dressing complies with the special controls identified in 21 CFR 878.4454. All of the size offerings are the manufactured with the same exact materials and formulation. The device meets the following performance specifications:

- Biocompatibility as per ISO 10993-1 for a device with prolonged patient contact duration (>24 hours to 30 days) for external communicating device with tissue/bone/dentin contact.
 - Cytotoxicity (L929 Neutral Red Uptake Method)
 - Irritation (Intracutaneous Injection)
 - Sensitization (Guinea Pig Maximization Sensitization Test)
 - Systemic Injection (Intravenous Injection and Intraperitoneal Injection – Acute Systemic Toxicity)
 - Implantation (Rabbit Implantation Tests – Tissue, Muscle, and Bone)
 - 4-week implantation study in subcutaneous tissue
 - 1-week implantation study in muscle
 - 4-week implantation study in muscle
 - 4-week implantation study in bone
 - 8-week implantation study in bone
 - Genotoxicity
 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
 - Chromosomal Aberration Study in Mammalian Cells
 - Peripheral Blood Micronucleus Study in Mouse
 - Additional Supporting Tests
 - Carcinogenicity (Clonal Transformation Assay using SHE Cells for 7-days)
 - Repeat Exposure System Toxicity for Kaolin (6-month animal survival study, custom test)
 - Systemic Intravenous Injection for Kaolin Extract
 - Systemic Intraperitoneal Injection for Kaolin Extract

510(k) Summary

Z-Medica, LLC QuikClot Control+® Hemostatic Dressing – Line Extension

▪ Pyrogen Test

- X-Ray Detectable Material - meets required specifications.
- Bench – the device meets the required specifications and acceptance criteria for tensile strength, elongation, clotting, and kaolin release.
- Preclinical Animal Study – Three GLP large animal (swine), to include a survival model, and one non-GLP study demonstrated the safety and effectiveness of QuikClot Control+. The studies included assessments such as hemostasis. In addition to hemostasis assessments, the animal survival study also conducted evaluations for blood chemistry (hematology, serum, coagulation), and macroscopic and microscopic tissue/organ examinations (adhesion, thromboembolism, kaolin migration). The cumulative animal study results support the safety and efficacy of the device.
- Stability – testing supports a 39-month expiration date.

Conclusion

The subject devices are identical to the predicate in terms of materials of construction, hemostatic agent used, mode of operation, scientific technological characteristics, indications for use and intended uses. Same as the predicate device, the new size options will be provided sterile utilizing existing validated packaging systems. The additional size offerings do not raise new types of questions of safety and effectiveness and is substantially equivalent to the predicate device.

SECTION 12: SUMMARY OF DEVICE TESTING

A. Performance Testing – Bench

All existing product specifications and performance criteria remain the same (refer to **Tables 1-3**). (b)(4)

(b)(4)

(b)(4) Regardless of the design (loop, size, plies, sewn, folded, pad, z-fold), both the subject and predicate devices undergo the same (b)(4) As such, the established product specification and performance criteria apply to the new configuration options.

B. Biocompatibility Testing

The biocompatibility results used to support clearance of the predicate device (DEN160012) also remain applicable. The subject device does not represent a new worse case configuration for biocompatibility as it does not contain any new material types than the predicate devices. Refer to **Table 4** below.

Table 4: Material Comparison of Predicate and Subject Devices

Materials	Configuration					
	Predicate (DEN160012)	Subject Device				
		1" x 1", 3 ply	4" x 2", 6 ply/10 ply	4" x 6", 6 ply/10 ply	4" x 8", 6 -10 plies	4" x 12", 9 ply
(b)(4)						

QuikClot Control+® is categorized as an externally communicating medical device that comes in contact with tissue/bone/dentin for >24 hours to 30 days as per ISO 10993-1, Biological Evaluation of Medical

Devices – Part 1: Evaluation and Testing Within a Risk Management Process. The biocompatibility data submitted with DEN160012 supported this classification and met all applicable requirements for the following parameter:

- Cytotoxicity (L929 Neutral Red Uptake Method)
- Irritation (Intracutaneous Injection)
- Sensitization (Guinea Pig Maximization Sensitization Test)
- Systemic Injection (Intravenous Injection and Intraperitoneal Injection – Acute Systemic Toxicity)
- Implantation (Rabbit Implantation Tests – Tissue, Muscle, and Bone)
 - 4-week implantation study in subcutaneous tissue
 - 1-week implantation study in muscle
 - 4-week implantation study in muscle
 - 4-week implantation study in bone
 - 8-week implantation study in bone
- Genotoxicity
 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay
 - Chromosomal Aberration Study in Mammalian Cells
 - Peripheral Blood Micronucleus Study in Mouse
- Additional Tests – Not required but executed to support clearance of the predicate device (DEN160012)
 - Carcinogenicity (Clonal Transformation Assay using SHE Cells for 7-days)
 - Repeat Exposure System Toxicity (28-day daily intraperitoneal dose of kaolin, custom test)
 - Systemic Intravenous Injection for Kaolin Extract
 - Systemic Intraperitoneal Injection for Kaolin Extract

(b)(4)

C. Performance Testing – Animal

In addition to the animal testing conducted for biocompatibility assessments, preclinical animal studies were performed and previously executed studies were leveraged to support clearance of the predicate device (DEN160012). Refer to **Table 5** for a list of the studies. In particular, large animal (swine) survival study (b)(4) evaluated the safety and efficacy of QuikClot Control+® in comparison to standard gauze. (b)(4)

(b)(4)

(b)(4) All analysis and results (b)(4)
 (b)(4)
 (b)(4) were comparable

between the control (standard gauze) and QuikClot Control+®.

All of the previously executed preclinical animal studies results remain relevant to the subject device.

Table 5: Pre-Clinical Animal Studies Evaluating the Safety & Effectiveness of Z-Medica’s Kaolin-Based Products

Study Number	Title	Summary	FDA Submission
(b)(4)	GLP Acute Hemostatic Evaluation Study of the Efficacy of D2 Hemostatic Dressing in the Swine Model	(b)(4)	510(k) K147057 and DEN160012
	GLP Acute Hemostasis Study in the Porcine Femoral Artery Injury Model		510(k) K147057 and DEN160012
	GLP Hemostatic Evaluation Study of the Safety of Prototype Hemostatic Dressings in the Swine Model		DEN160012
	Kaolin-based hemostatic dressing improves hemorrhage control from a penetrating inferior vena cava injury in coagulopathic swine. <i>J Trauma</i>		DEN160012

Study Number	Title	Summary	FDA Submission
(b)(4)	<i>Acute Care Surg.</i> 2017; (183)(1): 71-76.	(b)(4)	

D. Performance Testing – Clinical

Not Applicable. As in the predicate device clearance (DEN160012) clinical testing is not required.

E. Software

Not applicable. QuikClot Control+® does not incorporate software or interfaces with software systems.

F. Electrical Safety and Electromagnetic Compatibility

Not Applicable. QuikClot Control+® does not use or contain electronics.

From: Stephens, Nicholas * [Nicholas.Stephens@fda.hhs.gov]
Sent: 1/23/2020 4:50:08 PM
To: sking@z-medica.com
Subject: K200167 eCopy Hold Notification
Attachments: ECopy Hold Letter K200167.pdf; ECopy Hold Att K200167.pdf



eCopy Hold Letter

1/23/2020

Soraya King, Director, Regulatory Affairs
Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492
UNITED STATES

Dear Soraya King:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K200167
Received: 1/23/2020
Applicant: Z-Medica, LLC
Device: QuikClot Control+

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, “eCopy Program for Medical Device Submissions” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>.

Please write the specific submission number identified above **AND** “Replacement eCopy” directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You should provide the complete content for the document, not just the corrected files or folders, in your replacement eCopy. **When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.**

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

Attachment

Attachment

Attachment for Submission Number(s):

K200167

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

(b)(4)

Z-MEDICA

It's QuikClot Or It's Not

26 March 2020

U.S. Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Ramesh Kapil Panguluri, Ph.D., Lead Reviewer, Office of Surgical and Infection Control Devices (OHT4).

Re: 510(k) #K200167 – QuikClot Control+® Hemostatic Dressing Line Extension for Additional Size Offering, Z-Medica LCC's Response to FDA's Additional Information Request.

Dear Dr. Panguluri,

Enclosed please find the response to FDA's additional information email request dated 24 March 2020 for Z-Medica's 501(k) #K200167. We believe the responses address all of the additional information and clarification requested. A copy of the request is included with this response. The responses are structured where the FDA's questions are listed first and italicized followed by Z-Medica's clarification.

Z-Medica, LLC is providing one (1) ecopy of this submission with this signed cover letter as per the *eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff* dated 16 December 2019. The signed cover letter is the only paper document included with this submission. All supporting information, to include an ecopy of the signed cover letter, are included in the USB drive. The additional information and clarification contains methods, data, and analysis of these data which Z-Medica, LLC considers Trade Secret, commercially privileged and confidential to Z-Medica, LLC. In accordance with 21 CFR §20.61, this information is not disclosable to the public as per the Freedom of Information (FOI) Act.

Thank you in advance for the review of this submission.

Respectfully submitting

(b)(6)

Soraya King

Director, Regulatory Affairs

Z-Medica, LLC

Cell: (b)(4)

Office: 203-774-7922

Page 1 of 1





Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVB
WO66 RM4604
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6303

Premarket Notification 510(k) Review

Date: April 22, 2020			
Reviewer: Ramesh K Panguluri			
Subject: Traditional 510(k)# K200167/S001			
Applicant: Z-Medica, LLC	Device Trade Name: QuikClot Control+		
Contact Name: Soraya King	Contact Title: Director, Regulatory Affairs		
Correspondent Firm: Z-Medica, LLC	Phone: (203) 980-6067 Email: sking@z-medica.com		
Received Date: March 27, 2020	Due Date: April 26, 2020		
Pro Code(s): POD Class: II Reg #: 878.4454	Reg Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use		
Predicate Devices:			
Submission#	Pro Code	Device Trade Name	Applicant
DEN160012	POD	D2 Dressing	Z-medica, LLC
K140757	FRO	D2 Hemostantic Dressing	Z-medica, LLC
Recommendation			
I recommend that the QuikClot Control+ is/are Substantially Equivalent (SESE)			

Review Summary

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Digital Signature Concurrence Table (Doc ID: 04500.14.00)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Ramesh C.
Panguluri -S

Digitally signed by Ramesh
C. Panguluri -S
Date: 2020.04.22 11:32:34
-04'00'



Department of Health and Human Services

Food & Drug Administration
Center of Device & Radiological Health
Office of Product Evaluation and Quality
10903 New Hampshire Avenue
Silver Spring, MD 20993

Consult Memorandum

Date: April 15, 2020

From: Kira L. Moore, DVM, Veterinary Medical Officer;
CDRH/OPEQ/OHT4/DHT4B/THT4B3, Plastic Surgery Implant Devices

To: Ramesh “Kapil” Panguluri, PhD; CDRH/OPEQ/OHT4/DHT4/THT4B3

Cc: Cindy Chowdhury, PhD, MBA, Acting Assistant Director;
CDRH/OPEQ/OHT4/DHT4B/THT4B3, Plastic Surgery Implant Devices

Subject: K200167/S001 – Animal Study Consult AI Resposne

Sponsor: Z-Medica

Device: QuikClot Control+ Hemostatic Dressing

(b)(5)

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(b)(5)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Kira Moore -S 2020.04.17 11:10:59 -04'00'
Branch Chief Sign-Off	