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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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.

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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.