December 14, 2022

Z-Medica, LLC
Rachel Rehl
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Suite 600
Morrisville, North Carolina 27560

Re: K220971
Trade/Device Name: QuikClot Control+® Hemostatic Dressing
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: November 11, 2022
Received: November 14, 2022

Dear Rachel Rehl:

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,

Katherine N. Trivedi
-S

Katherine Trivedi
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220971

Device Name
QuikClot Control+® Hemostatic Dressing

Indications for Use *(Describe)*
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.

Cardiac surgical procedures: for temporary control of mild and moderate bleeding in cardiac surgical procedures, as well as in patients displaying class III or class IV bleeding.

Bone surfaces following sternotomy: to control bleeding from bone surfaces following a sternotomy.

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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510(k) SUMMARY

QuikClot Control+® Hemostatic Dressing – Expanded Indications

1. Submitter Information

Name: Z-Medica, LLC
Address: 4 Fairfield Boulevard
Wallingford, CT 06492
Contact Person: Rachel Rehl
Telephone Number: (919) 433-2588
Email: rachel.rehl@teleflex.com

Date Prepared: November 7, 2022

2. Device Name

Device Trade Name: QuikClot Control+® Hemostatic Dressing
Common Name: Temporary, Internal Use Hemostatic Wound Dressing
Classification Name: Non-absorbable, hemostatic gauze for temporary internal use. (Class II, POD, 21 CFR 878.4454)

3. Predicate Device

QuikClot Control+® Hemostatic Dressing (K200167)

4. Device Description and Mechanism of Action

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 and configurations. The device is available in single or multipacks.

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.

5. 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.

Cardiac surgical procedures: for temporary control of mild and moderate bleeding in cardiac surgical procedures, as well as in patients displaying Class III or class IV bleeding.

Bone surfaces following sternotomy: to control bleeding from bone surfaces following a sternotomy.

6. Technological Characteristics and Substantial Equivalence

The proposed device is identical to the predicate device described in K200167 in design, materials of construction, functional performance, principles of operation, manufacturing, packaging, sterilization, and shelf life.

The change to the device is an expansion of the indication for use. **Table 1** below provides a comparison of the proposed and predicate devices.

Table 1. Substantial Equivalence Comparison to Predicate

	Proposed Device QuikClot Control+® Hemostatic Dressing (Expanded Indications)	**Predicate Device – K200167** QuikClot Control+® Hemostatic Dressing	**Comparison**
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. Cardiac surgical procedures: for temporary control of mild and moderate bleeding in cardiac surgical procedures, as well as in patients displaying Class III or class IV bleeding. Bone surfaces following sternotomy: to control bleeding from bone surfaces following a sternotomy.	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.	Addition of indication for cardiac surgical procedures and bone surfaces. Indications align with proposed indications under IDE G200086.
Intended Use	To control internal and external bleeding To control bone surface bleeding at the sternotomy access site. To control suture line bleeding following cardiac surgical procedures, such as but not limited to, heart valve repairs or replacements, coronary artery bypass graft surgery (CABG), or aortic aneurysm repairs. To control bleeding due to tears, lacerations, and abrasions to include	To control internal and external bleeding	Addition of specific intended use for cardiac surgical procedures and bone surfaces that aligns with intended use under IDE G200086.

	Proposed Device QuikClot Control+® Hemostatic Dressing (Expanded Indications)	**Predicate Device – K200167** QuikClot Control+® Hemostatic Dressing	**Comparison**
	epicardial repairs with or without sutures. To be used with or without the use of cardiopulmonary bypass systems. The dressing can be applied to control bleeding while the patient is 'on or off pump'. To be used with or without autotransfusion (blood salvage) equipment. To be used on patients on anticoagulation / antiplatelet medication		
Contraindication	Do not leave QuikClot Control+® in place for more than 48 hours. QuikClot Control+® is not indicated for intraluminal vascular use.	Do not leave QuikClot Control+® in place for more than 48 hours. QuikClot Control+® is not indicated for intraluminal vascular use.	Same
Materials of Construction	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Same
Sizes	Various sizes including 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 5" x 5", 4 ply 8" x 8", 2 ply 12" x 12", 3 ply 3" x 4 yards, 1 ply 3" x 2 yards, 1 ply	Various sizes including 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 5" x 5", 4 ply 8" x 8" , 2 ply 12" x 12", 3 ply 3" x 4 yds, 1 ply	Addition of 1 proposed size (3" x 2 yards, 1 ply).
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Shelf-life	39 months	39 months	Same
Single Use	Yes	Yes	Same

	Proposed Device QuikClot Control+® Hemostatic Dressing (Expanded Indications)	**Predicate Device – K200167** QuikClot Control+® Hemostatic Dressing	**Comparison**
Packaging	Peelable foil pouch	Peelable foil pouch	Same
Biocompatibility	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Same

7. Pre-Clinical Animal Studies

Five GLP preclinical studies were conducted supporting the use of the device. This includes four GLP large animal (swine) studies including several survival models and a 12-week bone evaluation study conducted on rabbits. An additional non-GLP was also executed. The pre-clinical animal studies demonstrated the safety and performance of QuikClot Control+®. The studies included assessments such as hemostasis, bone regrowth, 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 substantial equivalence of the device.

8. Clinical Study

Clinical study, IDE #G200086, was conducted to support this premarket notification for the proposed expanded indications for the legally marketed QuikClot Control+® Hemostatic Dressing (K200167). The clinical trial was a prospective, randomized, open-label, multicenter, pivotal, evaluation of subjects undergoing elective cardiac surgical procedures. The objective of the study was to assess QuikClot Control+® Hemostatic Dressing in the treatment of mild and moderate bleeding during cardiac surgeries and on bone due to a sternotomy is as safe and effective as the control (standard gauze, disposable surgical sponges or lap sponges). 231 subjects were randomized and treated at a 2:1 ratio (test article to control). 153 subjects were treated with QuikClot Control+® (test article) and 78 subject with standard gauze (control). In addition, 21 roll-in subjects, 3 per site, were not randomized and treated with QuikClot Control+®.

The eligible subject population were ≥ 18 years of age, willing to give prior written informed consent, and required open heart surgery. Subject demographics were similar between groups. Mean age was 64.5 ± 12.2 years and subjects were predominantly male (68.8%) and Caucasian (94.8%). Categories of baseline medications were balanced between randomized arms. Of note, 41/153 (26.8%) QuikClot Control+® subjects and 17/78 (21.8%) control subjects were on an anticoagulant medication (P=0.258). Accordingly, a higher proportion of QuikClot Control+® subjects had baseline INR >1.1 (19/91=21%) compared to the standard gauze arm (7/47=15%). All baseline subjects completed blood count measurements and vital signs were balanced between randomized arms, except for systolic blood pressure (BP; QuikClot Control+® 135.5 ± 19.5; control: 141.4 ± 21.1; P = 0.037). The use of QuikClot Control+® Hemostatic Dressing during a sternotomy case or cardiac surgeries is intended to be used where surgical wounds result in mild and moderate bleeding throughout the procedure. As such, the surgical wounds evaluated in the trial were created at the sternotomy access site, suture lines (as part of the repair with native or synthetic material), tears, lacerations, abrasions, and epicardial repairs

(with or without sutures). The injury types that were evaluated in the study are typical in cardiac surgical procedures, such as:

- Coronary artery bypass graft (CABG) with or without valve repair/replacement – open heart sternotomy, thoracotomy or mini sternotomy
- Valve repair/replacement – open heart sternotomy, thoracotomy, or mini-sternotomy
- Aortic aneurysm surgery

During the mentioned surgeries, wounds that meet the mild (grade 1) or moderate (grade 2) bleeding severity criteria will have either QuikClot Control+® or control (i.e., standard gauze) applied during one of the injury types below:

- Sternal bleeding
- Suture line bleeding (native tissue or synthetic material)
- Tears, lacerations or abrasions to include epicardial repairs with or without sutures

The primary and secondary endpoints are described below:

- Primary endpoint: Rate at which subjects achieve hemostasis (grade 0 bleed) through up to 10 minutes of application and compression at the bleeding site.
- Secondary endpoint: Proportion of subjects achieving hemostasis (grade 0 bleed) measured at 5 and 10 minutes of application and compression at the bleeding site.

QuikClot Control+® achieved clinical hemostasis in cardiac surgery for mild to moderate bleeding as compared to control (i.e., standard gauze). The safety of QuikClot Control+® was comparable to control (i.e., standard gauze). The clinical investigation evaluated the expanded indications for use and intended uses described in **Table 1** above with confirmation that the subject device is substantially equivalent for its intended use.

9. Conclusions

The subject device is identical to the predicate in terms of materials of construction, hemostatic agent used, formulation, performance specifications, mode of operation/mechanism of action, scientific technological characteristics, and shelf-life. Design modifications or manufacturing process changes were not required to support the additional labeling. All previously executed performance testing (animal, biocompatibility, bench, stability) remain applicable. In conclusion, the subject device is the exact same as the predicate device. The subject device retained the same device properties as the predicate. The additional animal and clinical studies to evaluate mild and moderate bleeding with the described following a sternotomy and/or during cardiac surgeries confirmed that QuikClot Control+® is substantially equivalent to the predicate.