Z-Medica Corporation
c/o Robert V. Packard
Director of Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

June 11, 2023

Re: K061767
Trade/Device Name: QuikClot 1st Response™ & QuikClot ACS+™
Regulatory Class: Unclassified
Product Code: QSY

Dear Robert V. Packard:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 19, 2006. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Z-Medica Corporation
% Mr. Robert V. Packard
Director of Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K061767
Trade/Device Name: QuikClot 1st Response™ & QuikClot ACS+™
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 22, 2006
Received: June 23, 2006

Dear Mr. Packard:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrer

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061767

Indications For Use

510(k) Number (if known): ~~TBD~~ K061767

Device Trade Names: QuikClot 1st Response™ & QuikClot ACS+™

Device Common Name: Advanced Clotting Sponge

Indications For Use:

This device is intended for temporary external use to control traumatic bleeding.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruhmp

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061767

K061767

510(k) Summary

JUL 19 2006

Trade Names:	QuikClot 1st Response™ & QuikClot ACS+™
Device Class:	Class 1
Classification Panel:	General and Plastic Surgery
Common Name:	Traumatic Wound Dressing
Classification Name:	Dressing
Classification Code:	FRO
Predicate Device:	QuikClot ACS™ Advanced Clotting Sponge 510(k) No. K051955
Submitted By:	Robert V. Packard, Dir. of Regulatory Affairs
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	+1-203-294-0000 x262
Prepared:	June 22, 2006

Description of Device

QuikClot 1st Response™ and QuikClot ACS+™ are essentially the same device, but in two different sizes. Both devices are mesh bags containing zeolite beads. The devices are vacuum packed in multi-layer pouches to ensure sterility and efficacy. Product attributes of the two sizes are provided in the table below.

Attribute	QuikClot 1st Response™	QuikClot ACS+™
Intended Use	For Temporary External Use To Control Traumatic Bleeding	For Temporary External Use To Control Traumatic Bleeding
Mesh Bags Per Unit	One	One
Net Weight of Zeolite	0.88oz	3.5oz
Mesh Bag Dimensions	3.5"x3.5"	10"x5"
Baffling	No baffles – 1 compartment with 3.5oz of zeolite	3 baffles—creating 4 compartments with 0.88oz of zeolite each
Primary Packaging	4.5"x4.5" multi-layer pouch, vacuum-packed	6"x6.5" multi-layer pouch, vacuum-packed
Sterilization	gamma sterilization – 25-50kGy (SAL = 10^{-6})	gamma sterilization – 25-50kGy (SAL = 10^{-6})

Intended Use of Device

For temporary external use to control traumatic bleeding (prescription only).

K061767

Summary of Technological Characteristics Compared to Predicate Device

This is a device modification of QuikClot ACS™ Advanced Clotting Sponge (K051955). Both sizes of the device modification make use of the same mesh fabric used for the predicate device, the same primary package construction, and the same production process. The following are improvements made to the predicate device:

1. The zeolite beads were reformulated to reduce the heat of adsorption. Although generation of heat remains an intimate part of zeolite's mechanism of action, the risk of burns to caregivers and patients has been eliminated by the device modification.
2. A blue silicone rod, Class VI medical grade, with barium sulfate has been added to each mesh bag. This change allows medical personnel to locate the mesh bag with an X-ray if accidentally left in a wound.
3. Baffles were added to the larger size mesh bag, 10"x5", to facilitate application of the zeolite beads to larger wounds.
4. Directions for use were simplified from the directions for the predicate device. The predicate device instructed the care giver to use pressure to control the bleeding first, and then apply the product if pressure failed to control bleeding. Since this device modification eliminates the risk of burns, the care giver is not instructed to control bleeding with pressure alone first.

Discussion of Data to Support Substantial Equivalence

ISO Standard 10993-1:1997 was followed for demonstrating biocompatibility of the component materials and the finished device—all passed. In order to substantiate that the risk of burns has been eliminated, in-vitro and in-vivo temperature measurements were made. In in-vitro testing, an excess of zeolite was mixed with water. The peak temperature was reduced from 190°F (predicate device) to 90°F (device modification). Care givers that evaluated the product in a pre-clinical animal wound model experienced a peak temperature of 106°F and agreed that the risk of burns was eliminated. Care givers described the heat generated as "warm".

In-vitro test data measuring the clotting time of whole blood was used to demonstrate that the device modification is not inferior in efficacy to the predicate device. The zeolite formulation used in the predicate device and the reformulated zeolite took less than 3 minutes to form a clot, while whole blood without zeolite took longer than 6 minutes to form a clot. In-vivo testing in various swine models was used to demonstrate substantial equivalence to the predicate device.

Conclusions

Based on the design, biocompatibility data, in-vitro test data, pre-clinical test results, and intended use, QuikClot 1st Response™ and QuikClot ACS+™ are substantially equivalent to the predicate device (QuikClot ACS™ - Advanced Clotting Sponge K051955).