Z-Medica Corporation
c/o Giacomo Basadonna, M.D., Ph.D.
4 Fairfield Boulevard
Wallingford, Connecticut 06492

June 11, 2023

Re: K070010
Trade/Device Name: QuikClot Sport™ and QuikClot Sport Silver™
Regulatory Class: Unclassified
Product Code: QSY

Dear Giacomo Basadonna, M.D., Ph.D.:

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 January 25, 2007. 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

Z-Medica Corporation
% Giacomo Basadonna, M.D., Ph.D.
4 Fairfield Boulevard
Wallingford, Connecticut 06492

JAN 25 2007

Re: K070010
Trade/Device Name: QuikClot Sport™ and Quikclot Sport Silver™
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 29, 2006
Received: January 3, 2006

Dear Dr. Basadonna:

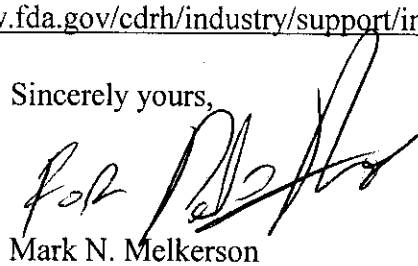
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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

Enclosure

Indications For Use

510(k) Number (if known): TBD K070010

Device Trade Names: QuikClot Sport™ & QuikClot Sport Silver™

Device Common Name: Advanced Clotting Sponge

Indications For Use:

QuikClot Sport™ & QuikClot Sport Silver™ are intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070010

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510(k) Summary

Trade Name:	QuikClot Sport™ and QuikClot Sport Silver™
Device Class:	Class 1
Classification Panel:	General and Plastic Surgery
Common Name:	Wound Dressing
Classification Name:	Dressing
Classification Code:	FRO, Unclassified
Predicate Device:	Hemosorb™ Granular Hemostatic Agent (K021581) QuikClot 1st Response™ Hemostatic Agent (K061767)
Submitted By:	Dr. Giacomo Basadonna, M.D., Ph.D.
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	(203) 294-0000 x233
Prepared:	December 29, 2006

JAN 25 2007

Description of Device

QuikClot Sport™ and QuikClot Sport Silver™ are OTC versions of Z-Medica's prescription product: QuikClot 1st Response™ (K061767). These new devices consist of mesh bags containing zeolite beads. The devices are vacuum-packed in multi-layer pouches to ensure sterility and efficacy. Product attributes of the two new OTC product versions are provided in the table below.

Attribute	QuikClot Sport™	QuikClot Sport Silver™
Antimicrobial	No	Silver causes >4-log reduction of *S. aureus*, *E. coli*, *P. aeruginosa*, and *C. albicans* within 60 minutes of exposure
Net Weight of Zeolite Beads	0.88oz & 1.75oz sizes available	0.88oz & 1.75oz sizes available
Mesh Bag Dimensions	3.5"x3.5" (0.88oz) & 5"x5" (1.75oz)	3.5"x3.5" (0.88oz) & 5"x5" (1.75oz)
Primary Packaging	Individually packaged in multi-layer pouch, vacuum-packed	Individually packaged in 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 stop bleeding of superficial wounds, minor cuts, and abrasions (Over-The-Counter Use).

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Summary of Technological Characteristics Compared to Predicate Devices

This is a device modification of QuikClot 1st Response™ Advanced Clotting Sponge (K061767). QuikClot Sport™ and QuikClot Sport Silver™ contain the same zeolite technology that Z-Medica Corporation has incorporated into previous QuikClot® brand hemostatic agents, granular QuikClot® (K013390/K021581) and QuikClot ACS™ (K051955), but this product uses zeolite that has been reformulated to reduce the heat of adsorption. The risk of burns to caregivers and the injured person has been eliminated by the zeolite reformulation.

Both sizes of QuikClot Sport™ and QuikClot Sport Silver™ 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 modifications have been made to the predicate device:

1. The X-ray detectable element has been eliminated (unnecessary for OTC version).
2. Directions for use were clarified from the directions for the predicate device. Instructions now include diagrams for each step of the instructions to assist untrained users.
3. The Silver version of the product contains silver that may reduce the risk of infection.

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. *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 these two new OTC products took less than 5 minutes to form a clot, while whole blood without zeolite took longer than 9 minutes to form a clot. Antimicrobial properties were demonstrated by *in-vitro* testing using cultures of *S. aureus, E. coli, P. aeruginosa,* and *C. albicans* (common infectious microorganisms). Exposure to QuikClot Sport Silver™ resulted in a greater than a 4-log reduction in viable organisms within 60 minutes.

Conclusions

Based on the design, biocompatibility data, *in-vitro* test data, and intended use, QuikClot Sport™ and QuikClot Sport Silver™ are substantially equivalent to the predicate device (QuikClot 1st Response™ (K061767) and granular QuikClot®/Hemosorb™ (K013390/K021581).