Z-Medica Corporation
Robert V. Packard
QA Manager
4 Fairfield Boulevard
Wallingford, Connecticut 06492

June 11, 2023

Re: K051955
Trade/Device Name: QuickClot ACS™ - "Advanced Clotting Sponge"
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 August 10, 2005. 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

AUG 10 2005

Mr. Robert V. Packard
QA Manager
Z-Medica Corporation
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K051955
Trade/Device Name: QuikClot ACS- "Advanced Clotting Sponge"™
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 18, 2005
Received: July 19, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting 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): K051955

Device Name: QuikClot ACS - "Advanced Clotting Sponge" ™

Indications For Use: QuikClot ACS - "Advanced Clotting Sponge"™, is intended for emergency use only as an external traumatic wound treatment to achieve hemostasis for moderate to severe bleeding.

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

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

...(k) Number K051955

K051955

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AUG 10 2005

510(k) Summary

Trade Name:	QuikClot ACS™ – "Advanced Clotting Sponge"
Device Class:	Class 1
Classification Panel:	General and Plastic Surgery
Common Name:	Traumatic Wound Dressing
Classification Name:	Dressing
Classification Code:	FRO
Predicate Device:	QuikClot® Brand Hemostatic Granules 510(k) No. K013390
Submitted By:	Robert V. Packard, QA Manager
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	(203) 294-0000
Prepared:	July 18, 2005

Device Description

The new mesh bags containing beads of QuikClot® Brand Hemostatic Agent, also called QuikClot ACS™ – "Advanced Clotting Sponge", are intended for emergency use as an external temporary traumatic wound treatment to achieve hemostasis and prevent blood loss.

The beads inside the mesh bags consist of a synthetic molecular sieve (zeolite) that accelerates the body's natural clotting processes by increasing the concentration of platelets and clotting factors at the wound site. Individual sieve particles of the hemostatic agent adsorb water molecules. As the water is removed from the blood, the platelets and clotting factors are concentrated. The platelets have been activated by the normal response to injury. This adsorption process is exothermic. The resultant increase in temperature at the site of application increases the rate of the clotting reactions and platelet aggregation and adhesion.

Both of the mechanisms described above, concentration of clotting factors and the increase in rates of platelet aggregation/adhesion, work together to increase the clotting rate. This would be consistent with what is known about the effects of temperature and concentration on coagulation enzyme activity and platelet function.

The product is designed and packaged to be easily packed, carried and applied using only one hand. It is well suited for moderate to large eviscerating wounds, to create hemostasis by coagulation.

Used in conjunction with direct pressure, QuikClot ACS™ reduces blood loss dramatically, and significantly increases survivability of high volume catastrophic wounds.

In-Vivo testing on swine was performed at four different institutions: Hartford Hospital in Connecticut, Portsmouth Naval Hospital in Virginia, the Naval Medical

Research Center (NMRC) in Maryland, and Uniformed Services University of the Health Sciences (USUHS) in Maryland. Tests demonstrated that the QuikClot ACS™ product performs at least as well as the current granular product in the swine femoral artery model. A summary of the NMRC testing is included with this pre-market submission.

This application for Special 510(k) clearance concerns the same hemostatic agent, in bead form, but the beads have been placed inside a synthetic mesh bag in order to facilitate easier application and removal of the product. This device modification retains the benefits of the previous device modification, granules vs. beads, but instead of removing individual beads from a wound medical personnel only need to remove the mesh bag containing the beads. Biocompatibility data for this device, and historical biocompatibility data for the components, is summarized in the appendices of this submission.

The intended use of the product remains the same, and the ACS product uses a similar method of application. Incorporation of the mesh bag presents some new potential failure modes for the device, but the Risk Analysis performed by the design development team indicates that the design and process controls used are sufficient to mitigate risks to an acceptable level and no additional actions are required. The risk analysis report for the ACS product is also included in the appendices of this submission.

QuikClot ACS™ is a safe, effective, low cost traumatic wound dressing which is substantially alike in purpose, characteristic, process, and result to the QuikClot® Brand Hemostatic Granules, and thereby eligible for approval under 510(k).