Z-Medica Corporation
Ronald Peterson
Director of RA/QA
4 Fairfield Boulevard
Wallingford, Connecticut 06492

June 11, 2023

Re: K072474
Trade/Device Name: QuikClot® eX™
Regulatory Class: Unclassified
Product Code: QSY

Dear Ronald Peterson:

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 October 16, 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
% Mr. Ronald Peterson
Director of RA/QA
4 Fairfield Boulevard
Wallingford, Connecticut 06492

OCT 16 2007

Re: K072474
Trade/Device Name: QuikClot® eX™
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 1, 2007
Received: October 2, 2007

Dear Mr. Peterson:

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): K072474

Device Trade Names: QuikClot® eX™

Device Common Name: Hemostatic Gauze Sponge

Indications For Use:

Prescription Use

QuikClot® eX™ is intended for temporary external use to control traumatic bleeding.

Over-The-Counter Use

QuikClot® eX™ is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

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)

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

510(k) Number K072474

510(k) Summary – K072474

OCT 16 2007

Trade Name:	QuikClot® eX™
Device Class:	Class 1
Classification Panel:	General and Plastic Surgery
Common Name:	Hemostatic Gauze Sponge
Classification Name:	Dressing
Classification Code:	FRO
Predicate Device(s):	QuikClot® Hemostatic Agent (K013390) QuikClot® Sport™ (K070010) Nu Gauze® All Purpose Dressing (K821150)
Submitted By:	Ronald E. Peterson, Dir. of Regulatory Affairs and QA
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	+1-203-294-0000 x262
Prepared:	August 31, 2007
Revised:	October 4, 2007

Description of Device

QuikClot® eX™ consists of standard non-woven medical gauze that has a clay mineral (Kaolin) bound to the gauze with Glycerin. Kaolin promotes hemostasis in a similar mechanism as QuikClot® Hemostatic Agent (K013390), but without the associated heat generation and risk of burning. QuikClot® eX™ is packaged as a four ply square sponge 4" x 4" sealed in a foil pouch and irradiated to a SAL of 10^{-6}. The foil package has the same material composition and construction as the QuikClot® Hemostatic Agent package.

Intended Use of Device

Prescription Use: QuikClot® eX™ is intended for temporary external use to control traumatic bleeding. Over-The-Counter Use: QuikClot® eX™ is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Discussion of Data to Support Substantial Equivalence

QuikClot® eX™ has been proven to clot whole sheep's blood faster than untreated controls during in-vitro testing, and has proven to be more effective during in-vivo testing of the swine model transection of the femoral vessels than untreated controls. QuikClot® eX™ has also proven to be effective in stopping bleeding of liver, spleen and mesenteric injuries, and has been successfully tested for biocompatibility in four separate laboratory tests.

Conclusion

Based on the in-vitro and in-vivo test data, and the biocompatibility data, QuikClot® eX™ is substantially equivalent in efficacy to the predicate devices (QuikClot® Hemostatic Agent (K013390) & QuikClot® Sport™ (K070010)) and in safety to Nu Gauze® All Purpose Dressing (K821150) and QuikClot® Sport™ (K070010).

Z-Medica Corporation 4 Fairfield Blvd., Wallingford, CT 06492, Tel: +1.203.294.0000, Fax: +1.203.294.0688
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