Emergency Medical Devices, LLC
c/o Jack Mentkow
Director
1875 Tulip Lane
Wellington, Florida 33414

July 28, 2023

Re: K082601
Trade/Device Name: UltraClot™, UltraClot™ OTC
Regulatory Class: Unclassified
Product Code: QSY

Dear Jack Mentkow:

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 9, 2008. 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

OCT 09 2008

Emergency Medical Devices, LLC
% Mr. Jack Mentkow
Director
1875 Tulip Lane
Wellington, Florida 33414

Re: K082601
Trade/Device Name: UltraClot™, UltraClot™ OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 5, 2008
Received: September 8, 2008

Dear Mr. Mentkow:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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

Enclosure

Section 4.

# Indications for Use

510(k) Number (if known): K082601

Device Name: UltraClot™, UltraClot™ OTC

Indications for Use:

Prescription, Rx
UltraClot™ is intended as a hemostatic dressing for emergency external use and temporary wound treatment to achieve hemostasis of moderate to severe bleeding.

Over the Counter, OTC
UltraClot™ OTC is intended as a topical hemostatic dressing for the local management of bleeding from minor cuts, lacerations, and abrasions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082601

OCT 09 2008

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**Emergency Medical Devices, LLC**
**P.O. Box 367**
**Loxahatchee, Florida 33470**
**Tel: 561-793-9773 / Fax: 561-795-9971**
**emeddevices@bellsouth.net**

Section 5.

# 510K Summary

**Submission Date:**

**Submitter Information:**

| | |
|---|---|
| Company Name: | Emergency Medical Devices, LLC |
| Company Address: | 1875 Tulip Lane,<br>Wellington, Florida 33414 |
| Contact Person:<br>Telephone:<br>Facsimile: | Jack Mentkow, Director<br>561-793-9773<br>561-795-9971<br>emeddevices@bellsouth.net |

**Device Information:**

| | |
|---|---|
| Trade Name: | UltraClot™, UltraClot™ OTC |
| Common Name: | Wound Dressing |
| Device Class: | Unclassified |
| Product Code: | FRO |

**Predicate Device:** QuikClot®, Z-Medica Corp., K013390
QuikClot® Sport, Z-Medica Corp, K070010

**Description:**

**Intended Use:** UltraClot™ is intended as a hemostatic dressing for emergency external use and temporary wound treatment to achieve hemostasis of moderate to severe bleeding.

**Intended Use:** UltraClot™ OTC is intended as a topical hemostatic dressing for the local management of bleeding from minor cuts, lacerations, and abrasions.

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**Device Description:**

UltraClot™ is a hemostatic agent comprising a clay-based powder contained in a dissolving pouch with a non-stick gauze pad backing that is placed on a moderate to severe wound and held in place until hemostasis is achieved. The device is packaged in a vacuum sealed foil bag and is provided sterile.

UltraClot™ was developed to address the need in both the military and civilian markets for a product that is both easy to use and effective. In the military application, UltraClot™ is effective in cases of moderate to severe bleeding leading to death due to uncontrolled hemorrhage, as a result of ballistic wounds and traumatic injuries. In the civilian market UltraClot™ is effective when there is a delay in receiving medical care. Traumatic injuries in the civilian market can occur from accidents in manufacturing, construction, farming, and sports activities.

**Comparison to Predicate Device:**

UltraClot™ has a similar adsorptive mechanism and indication for use as Quikclot®. Both devices rapidly adsorb the water content of the blood thereby concentrating the platelets and other coagulating factors, accelerating clotting and hemostasis.

UltraClot™ has been tested in animal models. UltraClot™ was found to be at least substantially equivalent to Quikclot® in terms of speed and efficacy with the added benefits of absence of exothermia and reduced blood loss.

Biocompatibility testing was performed on UltraClot™ which demonstrated UltraClot™ to be safe for its intended use. These included mutagenicity, cytotoxicity, and intracutaneous studies.

UltraClot™ OTC is very similar to UltraClot™. The adsorptive mechanism and indications for use in emergency wound care remain unchanged. The indications for use of UltraClot™ OTC have been modified from the Rx version, and the labeling has been revised in conformance with 21CFR 801 Subpart C. This labeling is modeled after and consistent with other legally marketed OTC wound management devices, including Woundstat® OTC (K081183), Quikclot® Sport (K070010), Medtrade Products Celox Topical Hemostatic granules OTC (K061079), Bleed Arrest (K070211), and Bloodstop (K071578).

Conclusion:
UltraClot™ is a safe and effective wound dressing which is at least substantially equivalent to the predicate device Quickclot®.

UltraClot™ OTC as labeled in conformance with 21CFR 801 Subpart C is substantially equivalent in labeling to the aforementioned OTC predicate devices, Woundstat® OTC (K081183), Quikclot® Sport (K070010), Medtrade Products Celox Topical Hemostatic granules OTC (K061079), Bleed Arrest (K070211), and Bloodstop (K071578).

Therefore, UltraClot™ and UltraClot™ OTC should be regulated by the FDA within the same respective generic types of devices which includes the cited predicate and OTC labeling and cleared for marketing in the U.S.