MedTrade Products, Ltd.
c/o Jonathan Ranfield
Director, Quality Assurance & Regulatory Affairs
Electra House, Crewe Business Park
Crewe, Cheshire, CW1 6GL
United Kingdom

June 11, 2023

Re: K061079
Trade/Device Name: MedTrade Products CELOX Topical Hemostatic Granules
Regulatory Class: Unclassified
Product Code: QSY

Dear Jonathan Ranfield:

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 June 2, 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

JUN - 2 2006

MedTrade Products, Ltd.
% Mr. Jonathan Ranfield
Director, Quality Assurance & Regulatory
Affairs
Electra House, Crewe Business Park
Crew, Cheshire CW1 6GL, UK

Re: K061079
Trade/Device Name: MedTrade Products CELOX Topical Hemostatic Granules
Regulation Class: Unclassified
Product Code: FRO
Dated: March 31, 2006
Received: April 20, 2006

Dear Mr. Ranfield:

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,

for 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)

Device Name: MedTrade Products CELOX Topical Hemostatic Granules

Indications for Use:

MedTrade Products CELOX Topical Hemostatic Granules are intended to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding.

Prescription Use_____X_____ AND/OR Over-The-Counter Use_ __
(Per 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)

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

510(k) Number K061079

Indications for Use

510(k) Number (if known)

Device Name: MedTrade Products CELOX Topical Hemostatic Granules OTC

MedTrade Products CELOX Topical Hemostatic Granules are intended to be available Over The Counter for the following indication.

Indications for Use:

MedTrade Products CELOX Topical Hemostatic Granules OTC are indicated for the local management of bleeding such as lacerations, minor cuts and abrasions.

Prescription Use_____ _____ AND/OR Over-The-Counter Use__X___
(Per 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)

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

510(k) Number K061079

SAFETY AND EFFECTIVENESS SUMMARY

MedTrade *Products* Ltd

Safety & Effectiveness: MedTrade CELOX Topical Hemostatic Granules

Classification Name: 878 – General and Plastic Surgery

Contact: Jonathan Ranfield - Director, Quality Assurance & Regulatory Affairs

Prepared: October 28, 2005.

Description: MedTrade CELOX Topical Hemostatic Granules are intended as a temporary external wound treatment for the control of severely bleeding wound for emergency use. MedTrade CELOX Topical Hemostatic Granules is intended for emergency use as an external temporary traumatic wound treatment to achieve Hemostatis and prevent blood loss. 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 hemolysis by coagulation.

Biocompatibility testing including: Dermal Irritation, Dermal Sensitisation, Cytotoxicity, Acute Systemic Toxicity, Hemolysis, has been conducted and results reported and discussed with the application.

The device is packed in a foil sachet and is provided sterile. It is sterilized by gamma irradiation The product will be sterilised by gamma irradiation in accordance with the Sterilisation of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilisation, 3rd Edition (ANSI/AAMI/ISO11137-1994) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991). Qualification will be based on Method 1 for dosimetric release with a sterility assurance level of 10^{-6}. The product will receive a dose of 25gKys to 35kGys.

MedTrade CELOX Topical Hemostatic Granules is substantially equivalent in chemistry and technology to: HemCon Incorporated, HemCon Bandage K023298 and in physical state and application to: On Site Gas Systems / Z-Medica's, QuickClot K013390

COMPARATIVE FEATURES

Characteristics	**MedTrade CELOX Topical Hemostatic Granules**	**HemCon's HemCon Bandage**	**On Site Gas System's / Z-Medica's QuickClot**
Chemistry	Chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine. This formulation has been self-affirmed by the manufacturer as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30.	Chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine. This formulation has been self-affirmed by the manufacturer as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30.	Not Applicable (As it is a synthetic derivative of volcanic rock)
Physical Composition	Granules / Granules	Not Applicable (As the Chitosan is made in to a foam)	Granules / Granules
Indications For Use	MedTrade CELOX Topical Hemostatic Granules is Hemostatic Granules for the external temporary control of severely bleeding wounds to achieve hemostasis and prevent blood loss, intended for emergency use. & OTC for Bleeding / Lacerations	HemCon Bandage is a Hemostatic dressing for the external temporary control severely bleeding wounds intended for emergency use. & OTC for Bleeding / Lacerations	QuickClot is intended for emergency use as an external temporary traumatic wound treatment to achieve hemostasis and prevent blood loss
Packaging	Foil Pouch	Foil Pouch	Foil Pouch
Sterilisation Method	Gamma Irradiation	Gamma Irradiation	Sterile

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CERT NO FM 53007
ISO 9001:2000
ISO 13485:2003