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

July 28, 2023

Re: K090780
Trade/Device Name: MedTrade Products CELOX Topical Hemostatic Paste OTC
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 November 20, 2009. 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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MedTrade Products Ltd.
% Mr. Jonathan Ranfield
Director, QA and RA
Electra House, Crewe Business Park
Crewe, Cheshire, CW1 6GI,
United Kingdom

Re: K090780
Trade/Device Name: MedTrade Products CELOX Topical Hemostatic Paste OTC
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 25, 2009
Received: October 5, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K090780

Indications for Use

510(k) Number (if known)

Device Name: CELOX Topical Hemostatic Paste

Indications for Use:

CELOX Topical Hemostatic Paste is indicated for the topical external temporary use to control moderate to sever bleeding and the local management of surface bleeding from vascular access sites and percutaneous tubes for catheters

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)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090780

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K090780

Indications for Use

510(k) Number (if known)

Device Name: MedTrade Products CELOX Topical Hemostatic Paste OTC

CELOX Topical Hemostatic Paste is intended to be available Over The Counter for the following indication.

Indications for Use:

CELOX Topical Hemostatic Paste OTC is indicated for the topical external temporary use to control bleeding of lacerations, minor cuts and abrasions.

It is intended for use to control minor bleeding and to absorb body fluid in superficial lacerations or wounds. Once exudation and bleeding have stopped, a protective dressing can be applied.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090780

2 of 2

K090780

Medtrade

Innovative Medical Products

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510(k) Safety and Effectiveness Summary: MedTrade CELOX Topical Hemostatic Paste

Classification Name: 878 – General and Plastic Surgery

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

Prepared: September 25, 2009.

Legally Marketed Device to which Equivalence is Claimed Celox Topical Hemostatic Granules K061079

Description: For OTC use MedTrade Product's CELOX Topical Hemostatic Paste OTC is indicated for the topical external temporary use to control bleeding of lacerations, minor cuts and abrasions. It is intended for use to control minor bleeding and to absorb body fluid in traumatic superficial lacerations or wounds. Once exudation and bleeding have stopped, a protective dressing can be applied.

For professional use CELOX Topical Hemostatic Paste is indicated for the topical external temporary use to control moderate to sever bleeding and the local management of surface bleeding from vascular access sites and percutaneous tubes for catheters.

The product is designed and packaged to be easily packed, carried and applied. It is well suited for low to moderate eviscerating wounds, to create hemolysis by coagulation.

The CELOX Hemostatic Paste is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of the adjunctive manual compression. The CELOX Hemostatic Granules then cause hemostasis in which a natural blood clot can build and form a physical barrier to bleeding.

MedTrade Products CELOX Topical Hemostatic Paste is provided in sterile tubes. Packaging will consist of between 1g to 50g of Paste.

Biocompatibility testing summary has been provided.

The device is packed in a tube 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 25 kGys to 35kGys.

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