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

July 28, 2023

Re: K080097
Trade/Device Name: Medtrade Products CELOX Hemostatic Granules On Sheet
MedTrade Products CELOX Hemostatic Granules OTC on Sheet
Regulatory Class: Unclassified
Product Code: QSY

Dear Jonathan D. 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 July 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

Medtrade Products Ltd.
% Mr. Jonathan D. Ranfield
Director, Quality Assurance
& Regulatory Affairs
Electra House, Crewe Business Park
Crewe, Cheshire CW1 6GL
United Kingdom

JUL - 9 2008

Re: K080097
Trade/Device Name: MedTrade Products CELOX Hemostatic Granules on Sheet
MedTrade Products CELOX Hemostatic Granules OTC on Sheet
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 30, 2008
Received: June 17, 2008

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

Enclosure

Indications for Use

510(k) K080097

Device Name: MedTrade Products CELOX Hemostatic Granules on Sheet

Indications For Prescription Use:

MedTrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control moderate to severe 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)

Barbara Brennan

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

510(k) Number K080097

Indications for Use

510(k) K080097

Device Name: MedTrade Products CELOX Hemostatic Granules OTC on Sheet

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

Indications For OTC (Over The Counter) Use:

MedTrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control bleeding of 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)

(Division Sign-Off)
Division of General, Restorative, Concurrence of CDRH, Office of Device Evaluation (ODE)
and Neurological Devices

510(k) Number K080097

MedTrade Products Ltd

K080097

510(k) SUMMARY: MedTrade CELOX Hemostatic Granules on Sheet

JUL – 9 2008

Classification Name: 878 – General and Plastic Surgery

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

Prepared: December 20, 2007

General Description: The MedTrade Products CELOX Hemostatic Granules on Sheet is nearly identical to the legally marketed MedTrade Products CELOX Hemostatic Granules (K061079, cleared April 20, 2006) in product design composition and processing in that the same CELOX Hemostatic Granules are mechanically heat bonded on to a viscose sheet. The Sheet provides a controlled and accurate delivery System to ensure that the CELOX Hemostatic Granules are applied directly onto the wound site as quickly and efficiently as possible. On contact with blood CELOX Hemostatic Granules that are heat bonded on to the surface of the viscose sheet cause hemostasis. The only major difference is the format in this respect; the indications for use are similar to the HemCon ChitoFlex Surgical (K071519) and Scion Cardio-Vascular Clo-Sur Plus PAD (K032986)

Indications for Use: For Prescription Use: MedTrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control moderate to severe bleeding.

For OTC (Over The Counter) Use:
MedTrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control bleeding of lacerations, minor cuts and abrasions.

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