



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: K091795
Trade/Device Name: MedTrade Products CELOX Trauma Gauze 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



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV 20 2009

Re: K091795

Trade/Device Name: MedTrade Products CELOX Trauma Gauze OTC
Regulation Number: Unclassified
Regulation Name: NA
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 29, 2009
Received: November 2, 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

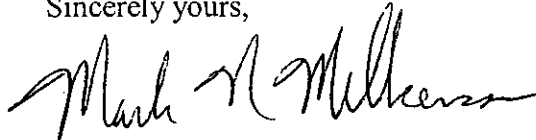
Page 2 – Mr. Jonathan Ranfield

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

K091795

Indications for Use

510(k) K091795

Device Name: MedTrade Products CELOX Trauma Gauze OTC

CELOX Trauma Gauze is intended to be available Over The Counter for the following indication.

Indications For OTC (Over The Counter) Use:

CELOX Trauma Gauze is indicated for temporary external use to control bleeding of lacerations, minor cuts and abrasions.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091795

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)

Indications for Use

510(k) Number K091795

Device Name: MedTrade Products CELOX Trauma Gauze

Indications For Prescription Use:

CELOX Trauma Gauze 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)

David Krane for MTH
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091795



2. 510(k) SUMMARY

Sponsor

MedTrade Products Limited
Electra House
Crewe Business Park
Crewe
Cheshire
CW1 6GL
UK

NOV 20 2009

Telephone: +44 1270 500019

Fax: +44 1270 500045

Registration Number: 9614493

Contact Person: Jonathan Ranfield

Date Summary was Prepared

June 12, 2009.

Device Information

Proprietary Name: CELOX Trauma Gauze
CELOX Trauma Gauze OTC

Common Name: Trauma Gauze

Classification Name: Dressing, Unclassified

Predicate Device

MedTrade Products Limited: CELOX Hemostatic Granules On Sheet (K080097)

HemCon: ChitoGauze (K090026)

Device Description

CELOX Trauma Gauze Rx & OTC is identical in composition to Aquanova Super Absorbent Dressing Rx & OTC cleared in K070175 on July 25, 2007 for:

(Rx) Under the supervision of a healthcare professional AQUANOVA may be used for wounds such as leg ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention.

AQUANOVA may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. AQUANOVA can be used in the control of minor bleeding.

Additionally, AQUANOVA may be used for exudate absorption in oncology wounds (e.g. fungating cutaneous tumours, cutaneous metastases and Kaposi's sarcomas).

(OTC) MedTrade Products AQUANOVA Super-Absorbent OTC is indicated for minor burns, superficial cuts, lacerations and abrasions, and minor irritations of the skin.



In vivo testing evaluated the efficacy of CELOX Trauma Gauze to provide hemostasis in femoral artery wound model. This data supports the effectiveness of the CELOX Trauma Gauze in achieving hemostasis in a femoral artery wound model. In addition the CELOX Trauma Gauze is substantially equivalent to other legally marketed chitosan based bandages with the same indications. With this 510(k) MedTrade is proposing to add the following indications to CELOX Trauma Gauze Rx and Celox Trauma Gauze OTC

CELOX Trauma Gauze Rx is indicated for temporary external use to control moderate to severe bleeding.

CELOX Trauma Gauze OTC is indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.

The predicate devices are indicated Rx for temporary external use to control moderate to severely bleeding wounds and OTC for temporary external use to control stop bleeding from minor wounds, minor cuts and minor abrasions. The CELOX Trauma Gauze is substantially equivalent to these predicate devices in that it has similar intended use and indications to the chitosan based predicate devices. The predicate devices are MedTrade Products Limited CELOX Hemostatic Granules On Sheet (K080097), cleared July 8, 2008 and HemCon: ChitoGauze (K090026), cleared March 31, 2009.

Indications for use

CELOX Trauma Gauze Rx is indicated for temporary external use to control moderate to severe bleeding.

CELOX Trauma Gauze OTC is indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.