Medtrade Products Ltd.
Claire Ryan
Head Of Regulatory and QA
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

April 21, 2023

Re: K113560
Trade/Device Name: CELOX Gauze PRO/CELOC PRO Hemostatic Gauze/OMNI-STAT Gauze/OMNI-STAT Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: QSY

Dear Claire Ryan:

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 August 1, 2012. 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 –WO66-G609
Silver Spring, MD 20993-0002

AUG 1 2012

Medtrade Products, Limited
% Ms. Claire Ryan
Head of Regulatory & QA
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

Re: K113560
Trade/Device Name: CELOX Gauze PRO/CELOC PRO Hemostatic Gauze/OMNI-STAT Gauze/OMNI-STAT Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 21, 2012
Received: June 25, 2012

Dear Ms. Ryan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113560

Device Name: **CELOX Gauze PRO / CELOX PRO Hemostatic Gauze / OMNI-STAT Gauze / OMNI-STAT Hemostatic Gauze**

Indications for Use:

Under the supervision of a healthcare professional **CELOX Gauze PRO / CELOX PRO Hemostatic Gauze / OMNI-STAT Gauze / OMNI-STAT Hemostatic Gauze for minor external bleeding from wounds and procedures** (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

Under the supervision of a healthcare professional **CELOX Gauze PRO / CELOX PRO Hemostatic Gauze / OMNI-STAT Gauze / OMNI-STAT Hemostatic Gauze for moderate to severe external bleeding wounds** (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.

Prescription Use __X_____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

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

510(k) Number K113560

INDICATIONS FOR USE

510(k) Number (if known): K113560

Device Name: **CELOX Gauze PRO (OTC)**

Indications for Use:

CELOX Gauze PRO (OTC) is indicated for use as a temporary topical dressing for minor cuts, minor abrasions, minor lacerations and minor burns.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ X ___ (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 Kwan for MH

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

510(k) Number K113560

AUG 1 2012

Section 5 – Traditional 510(k) Notification:- Summary

This Traditional 510(k) notification is to provide substantial equivalence for Medtrade Products CELOX Gauze PRO, which is substantially equivalent to currently marketed device intended for wound care.

Submitted by:-
Medtrade Product Ltd
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

Contact:-
Mrs Claire Ryan
Head of Regulatory and QA
Telephone: + 44(0)1270 500019
Fax:- + 44(0)1270 500045
Email: claire.ryan@medtrade.co.uk

Date prepared:- 26th March 2012

Proprietary Name: CELOX Gauze PRO

Common Name:-
CELOX Gauze PRO (Prescription)
CELOX Gauze PRO OTC
CELOX PRO Hemostatic Gauze (Prescription)
OMNI-STAT Gauze (Prescription)
OMNI-STAT Hemostatic Gauze (Prescription)
OMNI-STAT Granules on Gauze (Prescription)

Trade Names:- Not yet defined

Product Code:- FRO

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Legally marketed device(s) for substantial equivalence comparison:-
CELOX Hemostatic Granules on Sheet, 510(k) # K080097 and CELOX PRO 510(k) # K093593, manufactured by Medtrade Products Ltd.

Device Description:-
CELOX Gauze PRO is identical to CELOX Hemostatic Granules on Sheet (510(k) # K080097) in product composition (raw materials), manufacturing processes and product performance. The device consists of a chitosan Haemostatic granules (CELOX PRO 510(k) # K093593) adhered onto a base fabric (non-woven gauze) using a hot melt adhesive.

CELOX Gauze PRO achieves the principle intended action of hemostasis by the providing a physical barrier to stop bleeding. By applying the CELOX Gauze PRO directly onto a wound and together with firm pressure the gel-like plug on dressing's surface creates a physical barrier which controls blood flow through the dressing to stop bleeding and reduce the risk of re-bleeding.

In addition because CELOX Gauze PRO absorbs water from blood, platelets are concentrated, resulting in activation of platelets to help stop bleeding and reduce the risk of re-bleeding

CELOX Gauze PRO is an effective solution that reduces time to haemostasis, even for patients on anticoagulants such as warfarin and heparin.

The CELOX Gauze Pro is packed in a three layer laminate pouch of polyester, aluminium and LDPE. The pouch provide an integral barrier that maintains dressing sterility post irradiation yet allows easy opening and aseptic dressing removal by the end user.

The CELOX Gauze PRO is available in various sizes ranging from 1" x 1" to 3" x 10ft.

Indications for use:
Under the supervision of a healthcare professional **CELOX Gauze PRO for minor external bleeding from wounds and procedures** (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

Under the supervision of a healthcare professional **CELOX Gauze PRO for moderate to severe external bleeding wounds** (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.

CELOX Gauze PRO (OTC) is indicated for use as a temporary topical dressing for minor cuts, minor abrasions, minor lacerations and minor burns.

Manufacturing:-
CELOX Gauze PRO is manufactured according to the product specifications and under good manufacturing practices (GMP). A risk analysis has been performed in accordance with BS EN ISO 14971 to identify possible failure mode during manufacturing and design. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

CELOX Gauze PRO meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

CELOX Gauze PRO are terminally sterilised by gamma irradiation to a sterility assurance level (SAL) of 10^{-6}.

Testing:-
Performance data for the CELOX Gauze PRO has been established using *in-vivo* testing and bench testing.

The biocompatibility of CELOX Gauze PRO has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with harmonised standards (ISO 11137-1 – Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices).

The biocompatibility and performance testing for the CELOX Gauze PRO has demonstrated that the device is safe and effective for the indications of use.

Statement of Substantial Equivalence:-
The indication for use and performance testing for the CELOX Gauze PRO is substantially equivalent to the predicate device; CELOX Hemostatic Granules on Sheet, 510(k) # K080097 and CELOX PRO 510(k) # K093593 manufactured by Medtrade Products Ltd in that they are indicated for topical application as an aid in the control of temporary external bleeding associated with minor to severely bleeding wounds.