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

July 28, 2023

Re: K102965
Trade/Device Name: CELOX Trauma Gauze Ag, CELOX Hemostatic Antibacterial Trauma Gauze, Omni-Stat Trauma Gauze Ag, Omni-Stat Hemostatic Antibacterial Trauma Gauze
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 December 8, 2010. 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

DEC - 8 2010

Medtrade Products Ltd.
% Mr. Jonathan Ranfield
Quality and Regulatory Director
Electra House, Crewe Business Park
Crewe, Cheshire SW1 6GL
United Kingdom

Re: K102965
Trade/Device Name: MedTrade Products CELOX Antibacterial Trauma Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 24, 2010
Received: October 05, 2010

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. 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

DEC - 8 2010

510(k) K102965

Device Name: MedTrade Products CELOX Antibacterial Trauma Gauze

Indications For Prescription Use:

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

CELOX Antibacterial Trauma Gauze may be used for the management of partial and full thickness wounds 1st and 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology and pressure ulcers/sores (partial and full thickness), surgical wounds and donor sites.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102965

K102965
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Medtrade

Innovative Medical Products

510(k) SUMMARY

CELOX Antibacterial Trauma Gauze

DEC - 8 2010

1. Submitter:

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

Telephone: +44 1270 500019
Fax: +44 1270 500045

Contact Person: Jonathan Ranfield, Quality & Regulatory Director
E-mail: Jonathan.Ranfield@Medtrade.co.uk

Registration Number: 9614493

Date Prepared: September 24, 2010

2. Device:

CELOX Antibacterial Trauma Gauze
(Silver containing Antibacterial Dressing)

Common / Usual Name: CELOX Trauma Gauze Ag
CELOX Hemostatic Antibacterial Trauma Gauze
Omni-Stat Antibacterial Trauma Gauze
Omni-Stat Trauma Gauze Ag
Omni-Stat Hemostatic Antibacterial Trauma Gauze

Classification Name: Dressing, Wound, Drug

3. Predicate Device:

AQUANOVA Ag K100693 (Medtrade Products)
CELOX Trauma Gauze K0917953 (Medtrade Products)

CELOX Antibacterial Trauma Gauze is substantially equivalent in raw materials and manufacturing route to Predicate Device, AQUANOVA Ag Super Absorbent Dressing cleared in K100693 on August 10, 2010.

And identical to Predicate Device, CELOX Trauma Gauze cleared in K091795 on November 20, 2009, with the difference being the addition of ionic Silver as the antibacterial agent.

It also has the same intended use and indications to the above predicate devices.

Therefore, the technological characteristics of the subject device are substantially equivalent to those of the predicate device and the indications for use of the subject device are substantially equivalent to the predicate device as they are both super-absorbent dressings with the addition of ionic silver, both products gel in the presence of fluids to absorb large quantities of exudate and produce a moist wound healing environment. Both dressings have the same indications for use.

4. Device Description

CELOX Antibacterial Trauma Gauze (Silver containing Antibacterial Dressing) is a soft, sterile, non-woven gauze dressing. The dressing is composed of Chitosan, Chitosan derivatives and structural materials with the addition of ionic silver. The silver ions present in the dressing help to inhibit bacterial growth in the dresssing. The dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist wound environment which is conducive to wound healing and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and the ability to inhibit bacterial growth in the dressing provided by the CELOX Antibacterial Gauze support the body's healing process.

Chitosan is a material consisting of polysaccharide polymer, poly-N-acetylglucosamine. A similar chitosan material has been self-affirmed as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30. The GRAS report refers to safety studies in human beings and several species of animals. The studies sited represent research on the safety and use of chitosan, which have been published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement in 21 CFR s 170.30 (a), that a general recognition of safety requires common knowledge about the substance throughout the scientific community. Several biomedical applications of chitosan have already been reported.

Chitosan has many advantages due to its non-toxicity and biodegradability without damaging the environment. It is a biocompatible material that breaks down slowly in to a harmless product, glucosamine that can be absorbed completely by the body.

5. Intended Use:
CELOX Antibacterial Trauma Gauze is indicated for temporary external use to control moderate to severe bleeding.

CELOX Antibacterial Trauma Gauze may be used for the management of partial and full thickness wounds 1st and 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology and pressure ulcers/sores (partial and full thickness), surgical wounds and donor sites.

6. Technological Characteristics:
CELOX Antibacterial Trauma Gauze is substantially equivalent to Medtrade Products AQUANOVA Ag, K1000693, cleared August 10, 2010 in product design, composition and processing. Furthermore, CELOX Antibacterial Trauma Gauze is a highly absorbent polysaccharide derived polymers with the addition of ionic silver as an antibacterial ingredient that helps inhibit bacterial growth in the dressing. The product was evaluated through standard biocompatibility tests (ISO 10993) and found to be acceptable. Antibacterial effectiveness was established through testing with appropriate organisms.