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

July 28, 2023

Re: K093519
Trade/Device Name: CELOX Vascular
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 January 14, 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 W-O66-0609
Silver Spring, MD 20993-0002

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

JAN 14 2010

Re: K093519
Trade/Device Name: CELOX Vascular
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 05, 2009
Received: November 13, 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

K093519

Indications for Use

510(k) Number (if known) K093519

Device Name: CELOX Vascular

Indications For Prescription Use:

CELOX Vascular is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 16French"

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

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

510(k) Number K093519

K093519

K093519 page 1 of 1

Medtrade

Innovative Medical Products

510(k) SUMMARY

JAN 14 2010

Trade Name:	CELOX Vascular
Device Class:	*Unclassified*
Classification Panel:	General and Plastic Surgery
Classification Name:	Dressing
Classification Code:	FRO
Predicate Devices:	CELOX Hemostatic Granules on Sheet (K080097) QuikClot Interventional hemostatic bandage (K090620) D-Stat Dry Hemostatic Bandage (K061219) ChitoFlex-Surgical dressing (K080818)
Submitted By:	Jonathan Ranfield, Director Quality Assurance & Regulatory Affairs
Company Name:	MedTrade Products Limited
Company Address:	Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL. UK
Telephone:	+44 1270 500019
Fax:	+44 1270 500045
Registration Number:	9614493
Prepared:	November 5, 2009.

Description of Device

CELOX Vascular is a kit that consists of a hemostatic pad and an optional adhesive bandage. The adhesive bandage is a *3M Tegaderm 4" x 4-3/4" bandage* (reference K973036), or equivalent self adhesive security bandage. The hemostatic pad is CELOX Hemostatic Granules on Sheet cleared in K080079 on July 9, 2008.

Intended Use of Device

Prescription use: CELOX Vascular is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 16French"

Discussion of Data to Support Substantial Equivalence

In pre-clinical porcine model testing, CELOX Vascular has demonstrated hemostasis following the removal of percutaneous vascular access catheters. The dressing successfully controlled all bleeding following 11 vascular access procedures when up to a 16French tissue dilator was used. CELOX Vascular dressing controlled bleeding as effectively as the D-Stat Dry.

CELOX Vascular is identical to CELOX Hemostatic Granules on Sheet cleared in K080079 on July 9, 2008, therefore the successful biocompatibility testing for CELOX Hemostatic Granules on Sheet also applies to the CELOX Vascular.

Conclusion

Based on the in-vivo test data and the device description, CELOX Vascular is substantially equivalent in indications for use and technology to the predicate devices CELOX Hemostatic Granules on Sheet (K080097) QuikClot Interventional hemostatic bandage (K090620) D-Stat Dry Hemostatic Bandage (K061219) and ChitoFlex-Surgical dressing (K080818)