Medtrade Products Ltd.
Andrew Whitton
Head of Regulatory Affairs
Electra House
Crewe Business Park
Crewe, CHESHIRE CW1 6GL
United Kingdom

April 21, 2023

Re: K161274
Trade/Device Name: Bondiloxs Topical Hemostatic Granules
Regulatory Class: Unclassified
Product Code: QSY

Dear Andrew Whitton:

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 18, 2017. 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 Center - WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

Medtrade Products Ltd.
Andrew Whitton
Head of Regulatory Affairs
Electra House
Crewe Business Park
Crewe, CW1 6GL GB

Re: K161274
Trade/Device Name: Bondiloxs Topical Hemostatic Granules
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 19, 2016
Received: December 23, 2016

Dear Andrew Whitton:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161274

Device Name
Bondiloxs Topical Hemostatic Granules

Indications for Use *(Describe)*
Bondiloxs Topical Haemostatic Granules is indicated for use as a temporary topical dressing for external bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate bleeding.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
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Medtrade
Innovative Medical Products

Section 5 – 510(k) Summary

This Traditional 510(k) notification is to provide the basis for determining substantial equivalence of the Medtrade Products Bondiloxs Topical Hemostatic Granules to the predicate device presented below.

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

Contact:- Dr Andrew Whitton
Head of Regulatory Affairs
Telephone: + 44 (0)1270 500019
Facsimile:- + 44 (0)1270 500045
Email: andrew.whitton@medtrade.co.uk

Date prepared:- 9th January 2016

Device Name: Bondiloxs Topical Hemostatic Granules

Common Name:- Hemostatic granules

Trade/Proprietary Names:- Not yet defined

Product Code:- FRO

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Legally marketed device(s) for substantial equivalence comparison:-
CELOX Pro, manufactured by Medtrade Products Ltd, and cleared under 510(k) number K093593.

Device Description:-
The product is a chitosan-based haemostatic agent presented in a granular form in a sealed pouch. It is applied directly to the source of bleeding in a topical wound and pressure applied for up to 3 minutes until hemostasis is achieved.

Bondiloxs Topical Hemostatic Granules achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, Bondiloxs Topical Hemostatic Granules quickly forms a strong seal that completely covers the wound.

Indications for use:
Bondiloxs Topical Haemostatic Granules is indicated for use as a temporary topical dressing for external bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate bleeding.

Comparison to the predicate device:
The technological characteristics of both the Bondiloxs Topical Hemostatic Granules and the predicate, Celox Pro, are described in the following table:

	Bondiloxs Topical Hemostatic Granules	**CELOX Pro**
Design	The product is a chitosan-based haemostatic agent presented in a granular form in a sealed pouch. It is applied directly to the source of bleeding in a topical wound and pressure applied until hemostasis is achieved. It achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, it quickly forms a strong seal that completely covers the wound.	The product is a chitosan-based haemostatic agent presented in a granular form in a sealed pouch. It is applied directly to the source of bleeding in a topical wound and pressure applied until hemostasis is achieved. It achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, it quickly forms a strong seal that completely covers the wound.
Material/chemical Composition	A chitosan-based hemostatic granulate.	A chitosan-based hemostatic granulate.
Indications for Use (Prescription/Rx only)	Indicated for use as a temporary topical dressing for external bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate bleeding.	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. Indicated for temporary external treatment for

	Bondiloxs Topical Hemostatic Granules	CELOX Pro
		controlling moderate to severe bleeding.
For single use	Yes	Yes
For prescription use (Rx only)	Yes	Yes
Method of sterilisation	Gamma Irradiation in accordance with ISO 11137	Gamma Irradiation in accordance with ISO 11137
Sterility assurance level	10^{-6}	10^{-6}
Biocompatibility testing completed in accordance with ISO 10993	Yes	Yes

The indications for use of the Bondiloxs Topical Hemostatic Granules are essentially identical to those of the predicate device, Celox Pro, but with the removal of the use on severe bleeding.

Both the Bondiloxs Topical Hemostatic Granules and the predicate, Celox Pro, are composed of the same raw materials but just in slightly different ratios.

Performance Data:
The following performance data were provided in support of the substantial equivalence determination.

Bench testing of the Bondiloxs Topical Hemostatic Granules and its packaging was conducted on all of the main performance characteristics. The performance of the Bondiloxs Topical Hemostatic Granules was also analysed in bench testing against the predicate device, Celox Pro, with regard to both the ability to form a gel plug and the adhesion strength of the plug to the site of bleeding.

Performance testing in porcine bleeding models was performed for both the Bondiloxs Topical Hemostatic Granules and Celox Pro. Representative wound models were used to test the performance in moderate bleeding situations of both the Bondiloxs Topical Hemostatic Granules and Celox Pro. The results demonstrate that the Bondiloxs Topical Hemostatic Granules and Celox Pro work equivalently well in stopping bleeding in this wound model.

The biocompatibility of the Bondiloxs Topical Hemostatic Granules has been demonstrated to be in compliance with the requirements of ISO 10993-1 (Biological Evaluation of Medical Devices). Specific analysis included cytotoxicity testing in line with ISO 10993-5, irritation and sensitization testing in line with ISO 10993-10 and systemic toxicity testing in line with ISO 10993-11.

Sterilization validation has been performed in compliance with 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 results of the biocompatibility and performance testing conducted on the Bondiloxs Topical Hemostatic Granules were adequate to support a determination of substantial equivalence to the predicate.

Summary Statement of Substantial Equivalence:-

The indications for use and performance testing for the Bondiloxs Topical Hemostatic Granules demonstrates that it is substantially equivalent to the predicate device; CELOX Pro (510(k) # K093593) manufactured by Medtrade Products Ltd.