November 17, 2023

Medtrade Products Ltd.
Mina Patel
Regulatory Affairs Manager
Electra House, Crewe Business Park
Crewe, CW1 6GL
United Kingdom

Re: K230589
Trade/Device Name: Celox Rapid X-Ray Gauze
Regulatory Class: Unclassified
Product Code: QSY
Dated: October 26, 2023
Received: October 27, 2023

Dear Mina Patel:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230589

Device Name
CELOX Rapid X-Ray Gauze

Indications for Use *(Describe)*
Celox Rapid X-Ray detectable Z-fold hemostatic Gauze is indicated for temporary external use to control moderate to severe bleeding. May also be indicate for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY

This Traditional 510(k) Premarket Notification is to provide the basis for determining substantial equivalence of the Medtrade Products Ltd Celox Rapid X-Ray Gauze to the predicate device Celox Rapid Gauze presented below:

**Submitter:**

Medtrade Product Ltd
Electra House, Crewe Business Park
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United Kingdom
Telephone: + 44 (0)1270 500019
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**Submitter Contact:**

Miss Kelsey Gomes
Senior Regulatory Affairs Specialist

**Primary Contact:**

Ms. Mina Patel
Regulatory Affairs Manager

**Date prepared:** 26 October 2023

**510(k) Type**: Traditional

## Device Information:

| | |
|---|---|
| Common Name: | Dressing – Hemostat |
| Trade/Proprietary Name: | CELOX Rapid X-Ray Gauze |
| | OMNI-STAT Rapid X-Ray Gauze |
| | Celox Rapid X-Ray detectable Z-Fold Hemostatic Gauze |
| Classification Panel: | General and Plastic Surgery |
| Product Code: | QSY |
| Classification Name: | Dressing, Wound, Drug |
| Device Class: | Unclassified |

## Predicate / Reference Device/s:

| | |
|---|---|
| Predicate 1 Device | Primary Predicate |
| Device Name: | CELOX Rapid Gauze |
| Company: | Medtrade Products Ltd |
| 510(k) Number: | K110386 |
| Product Code: | QSY |

| | |
|---|---|
| Predicate 2 Device | Secondary Predicate |
| Device Name: | Prometheus ChitoGauze XR Pro |
| Company: | HemCon Medical Technologies |
| 510(k) Number: | K153582 |
| Product Code: | QSY |

| | |
|---|---|
| Reference 1 Device | Reference Device |
| Device Name: | Celox Hemostatic Granules on Sheet |
| Company Name: | Medtrade Products Ltd |
| 510(k) Number: | K080097 |
| Product Code: | QSY |

## Description of the Device:

Celox Rapid X-Ray Gauze is a sterile, single-use hemostatic gauze for external use. The gauze is stitch-bonded with a radiopaque strip and coated in chitosan-based hemostatic granules. The device is intended to control bleeding by forming a gel-like plug at the site of bleeding. Celox Rapid X-ray Gauze will be packaged in a tear-pouch for the pre-hospital market and a peel pouch for the hospital market and is available by prescription only. The subject device is a modification to the legally marketed predicate device Celox Rapid Gauze, with the inclusion of an x-ray detectable strip.

Celox Rapid X-Ray Gauze achieves its principle intended action (hemostasis) whereby the chitosan – hemostatic granules laminated to the gauze absorb blood and water creating a gelling action physically sealing the bleed site. As the water is absorbed, blood components are also amalgamated, in combination with manual pressure to the wound forming a gel coagulum at the site of bleeding. The device may be left in place for up to 72 hours. An additional standard gauze may be used if required.

## Intended Use and Indications for Use:

### Intended Use

Temporary topical external hemostat to control bleeding.

### Indications for use

**Prescription (Rx) Use:**
Celox Rapid X-Ray detectable Z-fold hemostatic gauze is indicated for temporary external use to control moderate to severe bleeding. May also be indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.

### Substantial Equivalence

Celox Rapid X-Ray Gauze has substantially equivalent indications for use, design principles, mechanisms of action and performance characteristics to the legally marketed primary predicate device Celox Rapid Gauze. The intended use of the subject device and primary predicate device are equivalent. The device is substantially equivalent in materials and performance characteristics, the addition of the radiopaque x-ray detectable strip does not alter the safety and performance of the device.

**Comparison of Technological Characteristics with the Primary Predicate Device:**

**Table 1:** Technological characteristics comparison of the subject device, primary predicate, and secondary predicate devices

| Category | Celox Rapid X-Ray Gauze (Subject Device) | Celox Rapid Gauze (Primary Predicate Device) | ChitoGauze XR Pro (Secondary Predicate Device) |
|---|---|---|---|
| 510(k) Number | K230589 | K110386 | K153582 |
| Product Code | QSY | QSY | QSY |
| Classification | Unclassified | Unclassified | Unclassified |
| Regulatory Class | Unclassified | Unclassified | Unclassified |
| For single use | Yes | Yes | Yes |
| Shelf-life | 5 years | 5 years | Unknown |
| Intended Use | Temporary topical hemostat to control bleeding | Temporary topical hemostat to control bleeding | HemCon ChitoGauze® XR Pro is a hemostatic dressing for the external, temporary control of severely bleeding wounds. |
| Indications for Use | Celox Rapid X-Ray detectable z-fold hemostatic gauze is indicated for temporary external use to control moderate to severe bleeding. May also be indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions. | Celox Rapid Gauze is a dressing indicated for temporary external use to control moderate to severe bleeding. | Prometheus ChitoGauze® XR PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds |
| Design | Celox Rapid X-Ray Gauze is a chitosan-based hemostatic guaze stitch bonded with an x-ray detectable strip using viscose Tencel, presented in a sealed trilaminate foil pouch. Th gauze materials consist of chitosan hemostatic granules bonded using a hot melt adhesive onto both sizes of the non-woven base gauze and cut to size. | Celox Rapid Gauze is a chitosan-based hemostatic gauze presented in a sealed trilaminate foil pouch. The gauze materials consist of chitosan hemostatic granules bonded using a hot melt adhesive onto both sides of the non-woven base gauze and cut to size. | Prometheus ChitoGauze® XR PRO is composed of standard polyester/rayon blend nonwoven medical gauze with a radiopaque filament that is coated with chitosan. The dressing is z-folded to the appropriate size and vacuum sealed in a pre-printed foil pouch. |

| | | | |
|---|---|---|---|
| Material/ Chemical Composition | A proprietary chitosan formulation in granular form heat bonded and coated on to both sides of a non-woven viscose-based gauze, stitch bonded with an x-ray detectable strip using a viscose (Tencel) thread. | A proprietary chitosan formulation in granular form heat bonded and coated on to both sides of a non-woven viscose-base gauze. | A chitosan covered standard non-woven base gauze with a radiopaque filament strip. |
| Size | Various:<br>3in x 2ft, 3in x 5ft, 1in x 5ft Ribbon. | Various:<br>Range from 1in x 1in" to 3in" x 10ft. | 3in x 4yd (7.5cmx 3.7m) |
| Method of sterilisation | Gamma Irradiation in accordance with ISO 11137 | Gamma Irradiation in accordance with ISO 11137 | Gamma Irradiation in accordance with ISO 11137 |
| For Prescription Use (Rx only) | Prescription use only | Prescription and OTC use | Prescription use only |

## Performance Data

### Non-Clinical Performance Data

The following Performance data was obtained via *in-vitro* testing carried out on both the subject device and the predicate devices, in line with Medtrade products Ltd Design Control process, in support of the modification to the indications of use from the primary predicate device.

1) pH
2) Wet Tensile and Elongation
3) Absorbency
4) Blood Immobilisation

All testing completed on both the subject device and primary predicate device meet the defined acceptance criteria. Comparison testing was performed on the secondary predicate device to support the devices being comparable.

### In-vivo Animal Studies

In-vivo studies included within this submission confirm that Celox Rapid X-ray Gauze can perform as intended under anticipated conditions of use and demonstrates efficacy in achieving hemostasis in various swine wound models with varying severities of bleeds. The gauze is easily removed following hemostasis being achieved and is readily detectable if inadvertently left.

### Biocompatibility Testing

Biocompatibility testing requirements has been assessed and evaluated to demonstrate compliance / in accordance with:

- ISO10993-1 *Biological evaluation of medical devices. Part 1- Evaluation and testing within a risk management process.*
- FDA guidance – *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".*
- USP <151> Pyrogenicity Test
- USP <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests
- FDA guidance - *Pyrogen and Endotoxins Testing: Questions and Answers*

As per standard guidance ISO 10993-1:2020 classification and FDA Biocompatibility guidance the subject device meets the requirements as a "*Surface Contact medical device that contacts breached and compromised skin, for a prolonged duration >24 hours to <30days*."

Material Mediated Pyrogenicity and Endotoxin testing has been assessed and meet the requirements of the relevant USP standards and FDA guidance documents.

Based on the comparison and substantial equivalence a sterilization justification has been provided to support Celox Rapid X-Ray Gauze being adopted into the Celox sterilization family to utilise the same sterilization process in accordance with BS EN 556-1:2001, ISO 11137:2017 and ISO 13485:2016 to achieve SAL of 1 x $10^{-6}$.

**Clinical Performance Data**

No clinical data was required for evaluation of this device.

## Conclusion:

The data contained within this submission and the conclusions drawn from these tests demonstrate that the subject device is as safe and effective as the predicate device and should perform as intended in the specified use conditions. Medtrade Products Ltd. has evaluated the intended use, mode of action, materials, technology, and performance specification of Celox Rapid X-Ray Gauze and has concluded that the subject device is substantially equivalent to the primary predicate device Celox Rapid Gauze, cleared under 510(k) #K110386.

Celox Rapid X-Ray Gauze is a rapid packing gauze to rapidly control and stop bleeding fast. Medtrade Products Ltd believes that as a result of the biocompatibility data, in-vitro testing and non-clinical animal testing, Celox Rapid X-Ray Gauze is safe and effective as an aid in the control of temporary external bleeding associated with moderate to severe bleeding and the control of minor external bleeding of lacerations, minor cuts and abrasions.