August 14, 2024

Cresilon, Inc.
Hassaan Ahmad
Vice President - Quality & Regulatory Affairs
86 34th Street
Suite D603/D604
Brooklyn, New York 11232

Re: K240713
Trade/Device Name: TRAUMAGEL® Hemostatic Gel
Regulatory Class: Unclassified
Product Code: QSY
Dated: July 11, 2024
Received: July 11, 2024

Dear Hassaan Ahmad:

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.
Assistant Director
DHT4B: Division of 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)*
K240713

Device Name
TRAUMAGEL®

Indications for Use *(Describe)*
TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Submitter Information

Sponsor and Application Correspondent (US Agent):	Hassaan W. Ahmad Vice President – Quality & Regulatory Affairs 86 34th Street, Suite D603/D604, Brooklyn, NY 11232
Phone	+1 347 269 1407
E-mail:	hassaan@cresilon.com
Legal Manufacturer:	Cresilon, Inc.
Phone:	+1 347 269 1407
Contact Person:	Hassaan W. Ahmad
E-mail:	hassaan@cresilon.com

Date Prepared:	14-Aug-2024

Device Identification:

Device Trade Name:	TRAUMAGEL®
Common Name:	Hemostatic wound dressing without thrombin or other biologics
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery
Product Code:	QSY
Regulation Number	Not Applicable

Predicate Device: CELOX Gauze Pro (K113560)

Device Description

TRAUMAGEL® is a single-use, hemostatic gel indicated for temporary external use only. The subject device is supplied as an individually pouched 30 mL hemostatic gel syringe, containing chitosan [poly (N-acetyl-D-glucosamine, D-glucosamine)] granules suspended in a sodium alginate hydrogel and is enclosed in a protective pouch. Each syringe is terminally sterilized with gamma

irradiation to a sterility assurance level (SAL) of 10^{-6}. The hemostatic gel is viscous, opaque and tan in color.

Indications for Use

TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.

Substantial Equivalence

The subject device TRAUMAGEL® is substantially equivalent to the predicate device CELOX Gauze PRO cleared under the 510(k) number, K113560. By evaluating the various technological characteristics along with its performance data, it is clear that the subject device is substantially equivalent to the predicate in terms of its design and technological characteristics. The subject device does not give rise to any new safety or performance questions when compared with its predicate CELOX Gauze PRO.

Substantial Equivalence (Technological Characteristics)

Parameters	**Subject device**	**Predicate Device**	**Comments**
Name	TRAUMAGEL®	Celox Gauze Pro	N/A
510(k) Number	K240713	K113560	N/A
Manufacturer	Cresilon Inc.	MedTrade Products, Ltd.	N/A
Product Code	QSY	QSY	Same
Device Class	Unclassified	Unclassified	Same
Intended/ Indications for use	TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.	Under the supervision of a healthcare professional CELOX Gauze PRO/ CELOX PRO Hemostatic Gauze/ OMNI-STAT Gauze/ OMNISTAT Hemostatic Gauze for moderate to severe external bleeding wounds (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.	Indication for use of TRAUMAGEL® are the same as that of primary predicate.
Rx/OTC	Rx	Rx	Same
Single Use	Yes	Yes	Same
Device Design	The hemostatic gel consists of chitosan granules suspended in a sodium alginate gel and is delivered via a syringe applicator	The device consists of chitosan hemostatic granules (CELOX PRO 510(k) # K093593) adhered onto a base fabric (non-woven gauze) using a hot melt adhesive.	Similar with CELOX Gauze PRO. TRAUMAGEL® is comprised of chitosan granules suspended within a sodium alginate gel, whereas Celox adheres chitosan granules to a non-woven gauze.
Packaged Size	30 mL of hemostatic gel in Syringe.	The CELOX Gauze PRO is available in various sizes ranging from 1" x 1" to 3" x l0ft.	N/A
Sterilization	Terminally sterilized with gamma irradiation SAL of 10^{-6}.	Terminally sterilized with gamma irradiation SAL of 10^{-6}.	Same
Mechanism of Action	When directly applied to a source of bleeding, the TRAUMAGEL® hemostatic gel rapidly adheres to the wound site. The hemostatic gel forms a mechanical barrier that stops the flow of bleeding and allows the body to create a natural clot.	CELOX Gauze PRO achieves the principle intended action of hemostasis by 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	Same

Non-clinical Testing:

The Subject Device has been evaluated through a series of nonclinical studies to determine whether the device meets the acceptance criteria for its intended applications. All the non-clinical tests conducted on the device are summarized below.

a) Biocompatibility Testing

Biocompatibility tests have been performed per the requirements of ISO 10993-1:2018 under the section "Surface devices used on breached or compromised surface with limited contact duration (≤24 hours)". The subject device complies with all the tests conducted and complies to the following standards identified in the below table.

Table 5 – Summary of Biocompatibility Testing Performed

Biological endpoint	Test Method	Purpose	Acceptance criteria	Test Result
Physical and/or Chemical Information	ISO 10993-1: Evaluation and Testing within a Risk Management Process	To know regarding formulation, manufacturing processes, geometric and physical properties and type of body contact and clinical use that is used to determine whether any additional biological or material characterization testing is needed	N/A	N/A
Cytotoxicity	ISO 10993-5: Tests for in vitro Cytotoxicity	To verify cytotoxicity potential of the subject device	Non-cytotoxic	Pass
Sensitization	ISO 10993-10: Tests for Skin Sensitization	To verify sensitization potential of the subject device	Non-sensitizing	Pass
Irritation	ISO 10993-23: Tests for Irritation.	To verify irritation potential of the subject device	Non-irritating	Pass
Material Mediated Pyrogenicity	ISO 10993-11: Tests for Systemic Toxicity	To verify the pyrogenicity potential of the device.	Non-pyrogenic	Pass
Acute Systemic Toxicity	ISO 10993-11: Tests for Systemic Toxicity	Evaluation of the potential for medical device materials to cause adverse systemic reactions.	Non-toxic	Pass

b) Performance Bench Testing

As a part of design verification studies, representative samples of the device underwent testing, including pH, rheology, safety and performance testing and other tests as applicable to the subject device.

c) Non-Clinical Animal Studies

In vivo animal performance testing was conducted in a porcine femoral arteriotomy model to evaluate both the predicate device and TRAUMAGEL®. The porcine model was used due to the vast similarities between pigs and humans when it comes traumatic injuries. Both the predicate and subject devices operate by the same mechanism of action. This

testing demonstrated substantially equivalent performance between the device and the predicate.

6.1 Sterilization and Shelf Life:

TRAUMAGEL® is terminally sterilized using gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.

The proposed shelf-life of the product is 12 months in the current submission.

6.2 Conclusion:

The intended use and the indications for use of the subject device, TRAUMAGEL®, are the same as that of the primary predicate. The technological characteristics of the subject device are the same as that of the predicate device CELOX Gauze PRO. Through the evaluation of the technological characteristics along with its performance and nonclinical test data, also using an additional predicate, Cresilon concludes that the subject device does not give rise to any new safety or performance concerns when compared to its primary predicate CELOX Gauze PRO.

The conclusions drawn above demonstrate that the proposed device is as safe, effective and performs as well as the legally marketed predicate device.