December 12, 2025

Cresilon, Inc.
Hassaan Ahmad
Chief Operating Officer
86 34th St.
Suite D603/D604
Brooklyn, New York 11232

Re: K253609
Trade/Device Name: TRAUMAGEL® 2.0 Hemostatic Gel
Regulatory Class: Unclassified
Product Code: QSY
Dated: November 14, 2025
Received: November 18, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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-Chiu 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253609

Device Name
TRAUMAGEL® 2.0 Hemostatic Gel

Indications for Use *(Describe)*
TRAUAMGEL® 2.0 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.

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Submitter Information:

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Legal Manufacturer:	Cresilon, Inc.
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Contact Person:	Hassaan W. Ahmad
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Device Identification:

Device Trade Name:	TRAUMAGEL® 2.0 Hemostatic Gel
Product Code Description:	Hemostatic Wound Dressing Without Thrombin or Other Biologics
Device Classification:	Unclassified Device (Pre-amendment)
Review Panel:	General & Plastic Surgery
Product Code:	QSY
Regulation Number:	Not Applicable

Indications of Use

TRAUMAGEL® 2.0 hemostatic gel is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.

Device Description:

TRAUMAGEL® 2.0 hemostatic gel contains chitosan granules suspended within a sodium alginate gel. The hemostatic gel is delivered via a syringe applicator. The chitosan is not dissolved within the sodium alginate gel. Chitosan does not delocalize from the hemostatic gel during application.

- The hemostatic gel contains two polymers: sodium alginate and poly (N-acetyl-D-glucosamine, D-glucosamine) (chitosan). These polymers are combined with water to form the hemostatic gel.
- The gel is viscous, opaque, and tan in color. The polymer components of the gel are non-animal, naturally derived, and as a result, syringe contents may appear darker over time.
- The hemostatic gel is intended for external application on breached and/or compromised skin.
- The hemostatic gel is pre-filled inside a sterile syringe and capped.
- The capped syringe is pouched and then terminally sterilized with gamma irradiation to a Sterility Assurance Level (SAL) 10^{-6}.
- The device is supplied as an individually pouched 30 mL hemostatic gel syringe.

TRAUMAGEL® 2.0 hemostatic gel is labeled for single-use-only. TRAUMAGEL® 2.0 is not intended to remain in contact with a patient for more than 24 hours following application. The hemostatic gel is not intended for surgical use, nor is it intended as a wound-closure device.

TRAUMAGEL® 2.0 hemostatic gel final product testing for batch release includes visual inspection, pyrogen testing, sterility testing, and rheology testing.

Substantial Equivalence:

List of Predicate Devices	510(k) Number	Type of Predicate
TRAUMAGEL® Hemostatic Gel	K240713	Primary Predicate
Cresilon Hemostatic Gel™ (CHG™)	K213652	Reference Predicate

TRAUMAGEL® Hemostatic Gel (K240713) is the primary predicate manufactured by Cresilon, Inc. Both the subject device and the primary predicate devices are intended for temporary external use for controlling moderate to severe bleeding. The indications for use, mechanism of action and hemostatic gel composition remains unchanged — when applied, the gel adheres to the wound site, forming a mechanical barrier that stops the flow of bleeding and allows the body to create a natural clot.

CHG™ (K213652) is included as an additional predicate as the hemostatic gel composition, and the syringe material remains the same as the subject device (TRAUMAGEL® 2.0).

S.No.	Parameters	TRAUMAGEL® 2.0 (Subject Device)	TRAUMAGEL® (Primary Predicate)	Cresilon Hemostatic Gel™ (CHG™) (Additional Predicate)	Comments/Remarks
1	510(k)	N/A	K240713	K213652	-
2	Regulation Number	Not applicable	Not applicable	Not applicable	-
3	Device Classification Name	Hemostatic wound dressing without thrombin or other biologics	Hemostatic wound dressing without thrombin or other biologics	Hemostatic wound dressing without thrombin or other biologics	Same
4	Product code	QSY	QSY	QSY	Same
5	Device class	Unclassified	Unclassified	Unclassified	Same
6	Intended use / Indications for use	TRAUMAGEL® 2.0 is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.	TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.	Cresilon Hemostatic Gel™ (CHG™) is a hemostatic gel for external use only. Cresilon Hemostatic Gel™ (CHG™) is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations, and minor abrasions	Same as Primary Predicate
7	Rx/OTC	Rx	Rx	Rx	Same
8	Single Use	Yes	Yes	Yes	Same
9	Device Design	Viscous Gel in Pre-Filled Syringe	Viscous Gel in Pre-Filled Syringe	Viscous Gel in Pre-Filled Syringe	Same

S.No.	Parameters	TRAUMAGEL® 2.0 (Subject Device)	TRAUMAGEL® (Primary Predicate)	Cresilon Hemostatic Gel™ (CHG™) (Additional Predicate)	Comments/Remarks
10	Mechanism of Action	TRAUMAGEL® 2.0 hemostatic gel is comprised of a proprietary blend of naturally derived polysaccharides, sodium alginate and poly (N-acetyl-D-glucosamine, D-glucosamine). Sodium alginate is a polyanionic polymer that forms a hydrogel in which poly (N-acetyl-D-glucosamine, D-glucosamine) particles are uniformly dispersed. When directly applied to a source of bleeding, the 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.	TRAUMAGEL® is comprised of a proprietary blend of polyanionic and polycationic polysaccharides. Sodium alginate is the primary polyanionic polymer, and poly (N-acetyl-D-glucosamine, D-glucosamine) is the primary polycationic polymer. Sodium alginate forms a hydrogel in which poly (N-acetyl-D-glucosamine, D-glucosamine) particles are uniformly dispersed. When directly applied to a source of bleeding, the 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.	CHG™ is comprised of a proprietary blend of polyanionic and polycationic polysaccharides. Sodium alginate is the primary polyanionic polymer, and poly (N-acetyl-D-glucosamine, D-glucosamine) is the primary polycationic polymer. Sodium alginate forms a hydrogel in which poly (N-acetyl-D-glucosamine, D-glucosamine) particles are uniformly dispersed. When directly applied to a source of bleeding, the 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.	Same as Primary Predicate
11	Syringe/Cap material composition	Material Composition 1. Syringe Barrel: Tritan™ Copolyester MX731 2. Syringe Cap: MAGNUM™ 8391 MED ABS Resin Natural 3. Plunger Rod: MAGNUM™ 8391 MED ABS Resin Natural 4. Rubber Stopper: Polyisoprene Synthetic Rubber 5. Lubricant: Polydimethylsiloxane oil	Material Composition 1. Syringe Barrel: USP Grade VI Grilamid TR 90 Natural (transparent thermoplastic polyamide) 2. Syringe Cap: USP Grade VI Polypropylene Bormed™ HD810MO 3. Plunger Rod: USP Grade VI Polypropylene Bormed™ HD810MO 4. Rubber Stopper: USP Grade VI Ethylene Propylene Diene Monomer	Material Composition 1. Syringe Barrel: Tritan™ Copolyester MX731 2. Syringe Cap: MAGNUM™ 8391 MED ABS Resin Natural 3. Plunger Rod: MAGNUM™ 8391 MED ABS Resin Natural 4. Rubber Stopper: Cis-isoprene Synthetic Rubber 5. Lubricant: Polydimethylsiloxane oil	Same as Additional Predicate.

S.No.	Parameters	TRAUMAGEL® 2.0 (Subject Device)	TRAUMAGEL® (Primary Predicate)	Cresilon Hemostatic Gel™ (CHG™) (Additional Predicate)	Comments/Remarks
			5. Lubricant: Dow Corning 360 Medical Fluid		
12	Pouching material	Pouch Material: Foil Pouch	Pouch Material: Foil Pouch	Pouch material: Tyvek® 1073B and PET-LDPE laminate	Same as Primary Predicate
13	Gel fill volume	30 mL of hemostatic gel.	30 mL of hemostatic gel.	5 mL of hemostatic gel.	Same as Primary Predicate
14	Sterilization process	Terminally sterilized with gamma irradiation SAL of 10^{-6}	Terminally sterilized with gamma irradiation SAL of 10^{-6}	Terminally sterilized with gamma irradiation SAL of 10^{-6}	Same
15	Product sterile barrier	Single Sterile Barrier (Syringe-Cap System)	Single Sterile Barrier (Syringe-Cap System)	Double Sterile Barrier (Syringe-Cap System and Pouch-System)	Same as Primary Predicate

Performance Testing Summary:
The subject device TRAUMAGEL® 2.0 has been evaluated through a series of V&V to determine if TRAUMAGEL® 2.0 meets the acceptance criteria for its intended applications. All the tests conducted on TRAUMAGEL® 2.0 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 following tests have been performed as per these requirements.

- ISO 10993-5: Tests for in vitro Cytotoxicity
- ISO 10993-10: Tests for Skin Sensitization
- ISO 10993-23: Tests for Irritation
- ISO 10993-11: Tests for Systemic Toxicity
- USP <151>: Pyrogen Test
- ISO 10993-12:2021: Sample preparation and reference materials
- ISO 10993-4:2017/AMD1:2025: Selection of tests for interactions with blood

b) Non - Clinical Testing
As a part of design verification studies, representative samples of the device underwent testing, including pH, force testing, gel volume, gel delivery time, and other tests as applicable.

c) Sterilization and Shelf Life:
TRAUMAGEL® 2.0 is terminally sterilized using gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}. The proposed shelf-life of the product is six (6) months.

Conclusion:
The intended use and indications for use of the subject device, TRAUMAGEL® 2.0 are the same as its primary predicate TRAUMAGEL® (K240713). The technological characteristics of the subject device are also substantially equivalent to its primary predicate. Based on the evaluation of technological characteristics and Verification & Validation test data, Cresilon concludes that the modifications do not raise any new safety or performance questions, and the subject device TRAUMAGEL® 2.0 is substantially equivalent to the legally marketed predicate device.