June 28, 2023

Cresilon, Inc.
Hassaan Ahmad
Vice President - Quality & Regulatory Affairs
87 35th Street, Suite 603/604
Brooklyn, New York 11232

Re: K213652/S003
Trade/Device Name: Cresilon Hemostatic Gel, CHG
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 1, 2022
Received: September 2, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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)*
To be assigned by FDA

Device Name
Cresilon Hemostatic Gel™ (CHG™), Cresilon Hemostatic Gel™, CHG™.

Indications for Use *(Describe)*
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.

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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510(k) Summary

1. **Submitter Information:**

Sponsor and Application	Hassaan W. Ahmad
Correspondent (US Agent):	Vice President – Quality & Regulatory Affairs 87 35th Street, Suite 603/604, Brooklyn, NY 11232
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Legal Manufacturer:	Cresilon, Inc.
Phone:	347 435 2226 x103
Contact Person:	Hassaan W. Ahmad
E-mail:	hassaan@cresilon.com
Date Prepared:	18th Nov 2021

2. **Device Identification:**

Device Trade Name:	Cresilon Hemostatic Gel™ (CHG™) Cresilon Hemostatic Gel™ CHG™
Product Code Description:	Dressing, Wound, Drug
Device Classification:	Unclassified Device (pre-amendment)
Review Panel:	General & Plastic Surgery
Product Code:	FRO
Regulation Number	Not Applicable

3. **Predicate Device:**

Table 1– List of Predicate Devices

Device Name	510(k) Number
Gel-E Flex Manufactured by Gel-E, Inc. (Now registered as Medcura, Inc)	K180152

4. **Device Description**

Cresilon Hemostatic Gel™ (CHG™) is a hemostatic gel for external use only, indicated for the local management of bleeding wounds such as minor cuts, minor lacerations, and minor abrasions.

CHG's hemostatic gel is comprised of poly(N-acetyl-D-glucosamine, D-glucosamine), sodium alginate, and water. CHG is supplied as individually pouched, sterile, pre-filled, single-use syringes. Each syringe is a single 5 mL hemostatic gel application. CHG is packaged in a box containing two (2) CHG applications.

After removal from the pouch, the cap is unscrewed, and the syringe is primed, the hemostatic gel is topically applied directly to the source of bleeding via the syringe.

5. Intended Use & Indications for Use

Intended Use: Cresilon Hemostatic Gel™ (CHG™) is a hemostatic gel for external use only.

Indications for Use: Cresilon Hemostatic Gel™ (CHG™) is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations, and minor abrasions.

6. Substantial Equivalence

The subject device Cresilon Hemostatic Gel™ (CHG™) is substantially equivalent to the predicate device Gel-E Flex cleared under the 510(k) number, K180152. The intended use and the indications for use of the subject device are same as that of the predicate and the technological characteristics such as, device design, physical state, mechanism of action and application of the device of the subject device are substantially equivalent to that of the predicate device Gel-E Flex.

Thus, CHG does not give rise to any new safety nor performance questions when compared with Gel-E Flex.

Table 2– List of Predicate Devices

	Device Name	**510(k) Number**
Predicate	Gel-E Flex	K180152

Table 3– Substantial Equivalence (Intended Use & Indications for Use)

Parameters	**Subject Device**	**Predicate Device**	**Comments**
Name	Cresilon Hemostatic Gel™ (CHG™)	Gel-E Flex	N/A
510(k) number	N/A-To be assigned by FDA	K180152	N/A
Intended Use	Cresilon Hemostatic Gel™ (CHG™) is a hemostatic gel for External use only.	The device is a hemostatic gel for External use only.	Same
Indications for use	Cresilon Hemostatic Gel™ (CHG™) is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations, and minor abrasions	Gel-e Flex is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions.	Same
Part of the body to be interacted with	Injured or breached skin	Injured or breached skin	Same
Single Use	Yes	Yes	Same
Rx/OTC	Rx	OTC	Cresilon intends to market CHG™ for prescription use (Rx). As CHG is intended for use by trained health care providers, CHG is equivalent to the predicate, as use error is minimized.

Table 4– Substantial Equivalence (Technological Characteristics)

Sr.No	Parameters	Subject device	Predicate Device	Comments
1.	Name	Cresilon Hemostatic Gel™ (CHG™)	Gel-E Flex (Gel)	N/A
2.	510(k) Number	N/A	K180152	N/A
3.	Manufacturer	Cresilon Inc.	Gel-E, Inc. (Now registered with FDA as Medcura, Inc.)	N/A
4.	Product Code	FRO	FRO	Same as predicate.
5.	Regulation Number	Unclassified	Unclassified	Same as predicate.
6.	Device Description	Cresilon Hemostatic Gel™ (CHG™) is a gel, composed of poly(N-acetyl-D-glucosamine, D-glucosamine) (Chitosan), sodium alginate, and water.	Gel-e Flex is composed of a gel of palmitoyl-N-acetylglucosamine (chitosan), dissolved in 0.1M lactic acid in water.	Both products have chitosan. Both products are delivered as viscous gels from pre-filled syringes. The animal efficacy testing data and the biocompatibility testing data do not raise additional questions about safety or efficacy of the subject device.
7.	Device Design/Technology	Viscous Gel in Pre-Filled Syringe	Viscous Gel in Pre-Filled Syringe	Same as predicate
8.	Volume	5 mL syringe	5 mL or 10 mL syringes.	Same as predicate
9.	Sterilization	10^{-6} SAL – Terminally sterilized with gamma radiation	10^{-6} SAL – Terminally sterilized with gamma radiation	Same as predicate
10.	Mechanism of Action	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 subject device	Same as Predicate
11.	Bench Testing	• Bench testing: pH, Viscosity • Animal efficacy testing	• Bench testing: pH, viscosity • Animal efficacy testing	Same as predicate.
12.	Biocompatibility	Cytotoxicity	Cytotoxicity	Similar

Sr.No	Parameters	Subject device	Predicate Device	Comments
		Sensitization Irritation/ Pyrogenicity Systemic Toxicity Hemolysis	Sensitization Irritation Pyrogenicity Systemic toxicity	
13.	Packaging	Bubble Testing Seal Strength Testing Dye Penetration Testing	Burst Pressure Testing Dye Penetration testing	Similar

7. **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 10993-1:2009, under the section "Surface devices used on breached or compromised surface with limited contact duration (≤24 hrs) ". 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**
Cytotoxicity	ISO 10993-5	To verify Cytotoxicity potential of the subject device	Non-cytotoxic	Pass
Irritation and Sensitization	ISO 10993-10	To verify irritation and sensitization potential of the subject device	Non-irritating and non-sensitizing	Pass
Pyrogenicity	ISO 10993-11	To verify the pyrogenicity of the device.	Non-pyrogenic	Pass
Acute Systemic Toxicity	ISO 10993-11:	Evaluation of the potential for medical device materials to cause adverse systemic reactions.	Non-toxic	Pass
Hemolysis	ASTM F756, ISO 10993-4	To verify the hemolytic property of the device.	Non-hemolytic	Pass

b) Performance Bench Testing

As a part of design verification studies, representative samples of the device underwent testing including packaging validation testing (Bubble Testing, Seal Strength Testing, Dye Penetration Testing and Removal Torque Testing) and *in vivo* animal efficacy testing.

In vivo animal efficacy testing was conducted in a porcine model of skin laceration to evaluate both the predicate device and Cresilon Hemostatic Gel™ (CHG™). The porcine model was used due to the vast similarities between pigs and humans when it comes to dermal wound lacerations. Both the predicate and subject devices operate by the same mechanism of action. In all instances, Cresilon Hemostatic Gel™ (CHG™) functioned as intended, device performance was as expected.

8. Sterilization and Shelf Life:

Cresilon Hemostatic Gel™ (CHG™) is terminally sterilized using gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.

Cresilon Hemostatic Gel™ (CHG™) is subjected to shelf-life testing to evaluate the shelf-life of the product for *in vivo* efficacy, container closure integrity, and deployment force.

9. **Conclusion:**

The intended use and the indications for use of the subject device, Cresilon Hemostatic Gel™, are the same as that of the predicate. The technological characteristics such as device design, physical state, mechanism of action, and application of the subject device are the same as that of the predicate device Gel-E Flex. The nonclinical test data further demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device. Based on the comparison above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.