May 22, 2024

Ushare Medical Inc.
℅ Joyce Yang
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, 518000
China

Re: K240097
Trade/Device Name: Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5)
Regulatory Class: Unclassified
Product Code: QSY
Dated: December 13, 2023
Received: January 12, 2024

Dear Joyce Yang:

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,

Mustafa A. Mazher -S

for Yu-Chieh Chiu, Ph.D.
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

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)*
K240097

Device Name
Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5)

Indications for Use *(Describe)*

Polysaccharide Hemostatic Powder is indicated for external temporary use as a topical dressing on minor 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.

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510(k) Summary

Date of Summary prepare: May 22, 2024

1. Submitter

Applicant Name	Ushare Medical Inc.
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2. Correspondent

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Post Code	518000
Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade/Proprietary Name:	Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5)
Common name:	Hemostatic Wound Dressing Without Thrombin Or Other Biologics
Review Panel:	General & Plastic Surgery
Product Code:	QSY
Device Class:	Unclassified

4. Legally Marketed Predicate Device

Trade Name	StopsBleeding™ Topical Hemostat Powder and Foam
Device Class	Unclassified
Review Panel	General & Plastic Surgery
510(k) Number	K140313
Product Code	QSY, LYA
Manufacturer	CoAg Medical LLC

5. Device Description

The Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) are sterile, topical wound dressings comprised of plant base polysaccharides. The hemostatic particles contained in powder absorb the water in the blood through physical adsorption, so that the blood components are concentrated to form a stable clot and achieve the purpose of hemostasis.

6. Intended Use/ Indications for Use

Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) is indicated for external temporary use as a topical dressing on minor bleeding wounds such as minor cuts, minor lacerations and minor abrasions.

7. Technological characteristics comparison

Comparison item	Subject Device: Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) (K240097)	Predicate Device: StopsBleeding™ Topical Hemostat Powder and Foam (K140313)	Comments
Product Code	QSY	QSY, LYA	Same
Classification	Unclassified	Unclassified	Same
Type of use	Prescription Use	Prescription Use, OTC	Same
Intended use & Indications for Use	Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) is indicated for external temporary use as a topical dressing on minor bleeding wounds such as minor cuts, minor lacerations and minor abrasions.	The CoAg Medical, LLC StopsBleeding™ Topical Hemostat Powder and Foam are intended for use as topical dressings for the management of bleeding wounds and are available for prescription use and over-the-counter use. Prescription: StopsBleeding™ Rx Topical Hemostat Powder and Foam are indicated for use as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and are also	Same

Comparison item	Subject Device: Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) (K240097)	Predicate Device: StopsBleeding™ Topical Hemostat Powder and Foam (K140313)	Comments
		indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites. StopsBleeding™ Rx is intended for use under the care of a health care professional. OTC: StopsBleeding™ OTC Topical Hemostat Powder and Foam are indicated for use as a topical dressing on minor bleeding wounds such as cuts, lacerations and abrasions and for minor nose bleeds.	
Applicable user	Medical professionals	Medical professionals, layman	Same
Single /repeat use	Single use	Single use	Same
Sterile /non-sterile	Sterile	Sterile	Same
Sterilization method and SAL	ETO sterile SAL=10^{-6}	Gamma radiation SAL=10^{-6}	Different (issue 1)
Materials	Sodium Starch Glycolate	Sodium Starch Glycolate	Same
Patient - contact potential (Duration and type of contact)	Breached or compromised surfaces, Up to 24 hours	Breached or compromised surfaces, Prolonged exposure of 24 hours to 30 days	Different (issue 2)

Issue 1: The sterilization procedure has been validated in accordance with ISO 11135:2014. Therefore, it can be considered that this difference does not introduce new risks

Issue 2: The subject device is intended for emergency hemostasis and requires debridement within 24 hours. The contact time between the product and the patient shall not exceed 24 hours. The contact nature of this product is limited contact. Biocompatibility tests have been conducted according to Guidance of Use of International Standard ISO 10993-1, for cytotoxicity, intracutaneous reactivity, sensitization, acute systemic toxicity, and material-mediated pyrogenicity. Therefore, it can be considered that this difference does not introduce new risks.

8. Summary of non-clinical testing

The Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) are sterilized by EO, and the sterilization procedure has been validated in accordance with ISO 11135:2014.

The shelf-life for two years had been validated in accelerated testing according to ASTM F1980-21 and the requirements on packaging for terminally sterilized medical device per ISO 11607-1:2006 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf-life test.

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and pyrogen tests were performed to demonstrate the biocompatibility of the device.

Design verification testing was performed on Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) to demonstrate the physical and functional requirements were met.

The safety and effectiveness study were performed on a porcine animal model demonstrate that the Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) performed substantially equivalent to the predicate device.

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the intended use and technological characteristics, supported by the non-clinical testing demonstrates that the subject device, Polysaccharide Hemostatic Powder (HP-2, HP-3, HP-5) are as safe and effective, and is substantially equivalent to the legally marketed predicate device cleared under K140313.