August 28, 2020

Solaplus Biotech Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai
Shanghai, 200120 Cn

Re: K192671
Trade/Device Name: Hemostatic Xerogel Sponge
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 29, 2020
Received: July 29, 2020

Dear Diana Hong:

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,

Anjana Jain, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K192671

Device Name
Hemostatic Xerogel Sponge

Indications for Use *(Describe)*
The Hemostatic Xerogel Sponge is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: __K192671__

1. Date of Preparation: 08/28/2020

2. Sponsor Identification

Solaplus biotech co., ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Subject Device

Trade Name: Hemostatic Xerogel Sponge
Common Name: Chitosan Wound Dressing
Models: XLJ-I, XLJ-I-1 and XLJ-I-4

Regulatory Information

Classification Name: Dressing, Wound, Drug
Classification: Unclassified
Product Code: FRO
Review Panel: General & Plastic Surgery

Indications for Use
The Hemostatic Xerogel Sponge is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Device Description:

The proposed device, Hemostatic xerogel sponge, is available in three models for different size.

The Hemostatic Xerogel Sponge is a irradiation sterilized, single used device, and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 2 years.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K153582
Product Name: Prometheus ChitoGauze® XR PRO
Manufacturer: HemCon Medical Technologies, Inc.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

Physical testing listed in following table were performed on the proposed device. The test results show that the device meets the requirements of related standards.

Item	Water Absorption	Density Test
Brief description	The samples were placed in glass dishes, and purified water was slowly added to the surface of the samples. After the samples were completely gelated, they were stabilized for 5min. Pour the purified water spilled in the glass dish and weigh it. Calculate the hydroscopicity.	Cut a piece of sample of a certain size, weigh it with an electronic balance and record it. After weighing it, measure its length, width and thickness with a vernier caliper, and calculate the density.
Purpose and objective	Test the subject device's absorbtion ability.	Test the subject device's density.
Acceptance criteria	The liquid absorption amount of each sample is not less than 20 times of the weight of the sample before liquid absorption.	Product density $\geqslant$ 0.2 g/ cm^3 which is specified based on the product technique requirements
Conclusions	The water absorption of Hemostatic Xerogel Sponge meets the acceptance criteria of this test item.	The density of Hemostatic Xerogel Sponge meets the acceptance criteria of this test item.

The package test methods include simulated distribution (ASTM D4169:2016) and associated package integrity testing (ASTM F88/F88-15 seal stength test and ASTM F1929-15 dye penetration test), as well as accelerated aging and associated package integrity testing, to validate package integrity and shelf life claims.

Sterilization testing listed in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. Endotoxin limit did not exceed 20EU/device.

Item	Standard
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>

Animal Sutdy

A new in vivo testing using swine femoral artery as a model is conducted one the subject device and predicate device to supports the indications for use of the subject device. The test results demonstrate that the subject device is substantially equivalent to the predicate device.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristic

Item	Proposed Device	Predicate Device K153582	Remark
Product Code	FRO	FRO	SE
Indication for use	The Hemostatic Xerogel Sponge is a hemostatic dressing for the external, temporary control of severely bleeding wounds.	Prometheus ChitoGauze ® XP PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds.	SE
Models/ size	XLJ-I: 80×60x5mm XLJ-I-1: 40×30×5mm XLJ-I-4: 120×80×5mm	4 inch by 4 inch 2 inch by 2 inch	SE Analysis 1
Product structure/ Material	a porous sodium polyacrylate-grafted chitosan sponge	Polyester/rayon blend non-woven gauze coated with chitosan	SE Analysis 2
Single Use	Yes	Yes	SE
Biocompatibility	Breached or compromised surface contact	Breached or compromised surface contact	SE
	cytotoxicity, sensitization, irritation, systemic toxicity, material-mediated pyrogenicity	cytotoxicity, sensitization, irritation, systemic toxicity	SE
Sterilization	Gamma irradiation	Gamma irradiation	SE
	10^{-6} SAL	10^{-6} SAL	SE
Labeling	complies with Title 21, CFR Section 801 labeling	complies with Title 21, CFR Section 801 labeling	SE

SE Analysis 1- Model/Size

The size of proposed device and predicate devices is different. The size will not affect the function and performance of the product. And the model of proposed device is listed in user manual, user can select appropriate model per requirement. Therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate device.

SE Analysis 2- Product structure/Material

The proposed device and predicate device have different product structure. The proposed device is a porous sponge, while the predicate device is a non-woven gauze. But they have the same main

material (chitosan) to control blood bleeding. In addition, biocompatibility test has been conducted on the propose device and the test result does not show any adverse effect. Based on above analysis, we think the difference on the Product structure/Material will not affect the Substantially Equivalency (SE) between the proposed and predicate device

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.