May 2, 2023

Hangzhou Zeo-Innov Life Technology Co., Ltd
Zhao Lijuan
Chief Executive Officer
101, Building 2, No.291 Fucheng Road
Hangzhou, Zhejiang 310018
China

Re: K223495
Trade/Device Name: Zeolite Hemostatic Cotton
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 31, 2023
Received: March 31, 2023

Dear Zhao Lijuan:

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,

Julie A. Morabito -S

Julie A. Morabito, Ph.D.
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)*
K223495

Device Name
Zeolite Hemostatic Cotton

Indications for Use *(Describe)*

Prescription Use: Zeolite Hemostatic Cotton is intended for temporary external use to control traumatic bleeding.

Over-The-Counter Use: Zeolite Hemostatic Cotton is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and 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.

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510(k) Summary

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

The assigned 510(k) Number: K223495

1. Date of Preparation: 04/24/2023

2. Sponsor Identification

Hangzhou Zeo-Innov Life Technology Co., Ltd.

101, building 2, No.291, Fucheng Road, Hangzhou, 310018, China

Establishment Registration Number: 600558

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3. Identification of Proposed Device

Trade Name: Zeolite Hemostatic Cotton

Common Name: Hemostatic Cotton

Regulatory Information

Product code: FRO

Classification Name: Dressing, Wound, Drug

Classification: Unclassified;

Review Panel: General and Plastic Surgery

Indication for Use:

Prescription Use: Zeolite Hemostatic Cotton is intended for temporary external use to control traumatic bleeding.

Over-The-Counter Use: Zeolite Hemostatic Cotton is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Device Description

The Zeolite Hemostatic Cotton consists of zeolite and cotton. It is provided in a sterile dressing format that conforms readily to the wound. There are 15 models of Zeolite Hemostatic Cotton, and the size ranges from 0.1g to 10g. The difference between each model is weight.

4. Identification of Predicate Device

510(k) number: K211570

Product Name: Zeolite Hemostatic Gauze

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M: 2021 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980: 2021 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F3039: 2015 Standard Test Method for Leakage of Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
- ASTM D3078:2002 (Reapproved 2021)e1 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- USP <85> Bacterial Endotoxins Test
- USP <151> Pyrogen Test (USP Rabbit Test)
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10: 2021 Biological Evaluation of Medical Devices-Part 10: Tests for Skin Sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation

The following performance data were provided in support of the substantial equivalence determination.

Physical performance testing

Three discrete batches of subject device were tested for water absorption, Zeolite content, and heat release. The water absorption of the devices is ≥10g, and the hydration temperature rise is ≤3.0℃. The Zeolite amount of the proposed device is not less than 10%. The physical performance test results all meet the requirements of the acceptance criteria.

Sterile barrier packaging testing were performed on the proposed device, which include visual inspection (ASTM F1886/F1886M: 2016), seal strength (ASTM F88/F88M: 2021), dye penetration test (ASTM F3039: 2015), vacuum leak (ASTM D3078:2002 (Reapproved 2021)e1) and sterility (ISO 11737-2:2019). The test result showed that the device package can maintain its integrity during a shelf life of 3 years.

Sterilization and shelf-life testing listed in following table were performed on the proposed device. Endotoxin limit did not exceed 20EU/10g. Accelerated stability test results showed that the device can maintain its performance meet the acceptance criteria during a shelf life of 3 years.

Bacteria Endotoxin Limit	USP <85>
Shelf-Life Evaluation	Appearance, water absorption, Zeolite content, heat release, and package integrity tests were performed on samples of after accelerated aging to verify the claimed shelf life of the device.

Biocompatibility testing

The contact level of the proposed device is breached or compromised surfaces, and the contact duration is limited contact (≤24 hours). The proposed device was evaluated for the following tests. The results for the biocompatibility testing showed that the proposed device is biocompatible.

- Cytotoxicity,
- Sensitization,
- Intracutaneous Reactivity,
- Acute Systemic Toxicity,
- Pyrogen testing.

6. Clinical Test

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device K223495	Predicate Device K211570	Comparison
Product Code	FRO	FRO	Same
Class	Unclassified	Unclassified	Same
Indication for Use	Prescription Use: Zeolite Hemostatic Cotton is intended for temporary external use to control traumatic bleeding. Over-The-Counter Use: Zeolite Hemostatic Cotton is intended for temporary external use to stop bleeding of superficial	Prescription Use: Zeolite Hemostatic Gauze is intended for temporary external use to control traumatic bleeding. Over-The-Counter Use: Zeolite Hemostatic Gauze is intended for temporary external use to stop bleeding of superficial	Same

	wounds, minor cuts, and abrasions.	wounds, minor cuts, and abrasions.	
Material	Cotton Zeolite	Gauze Zeolite	Analysis 1
Single Use	Yes	Yes	Same
Size	0.1g, 0.2g, 0.3g, 0.4g, 0.5g, 0.6g, 0.7g, 0.8g, 0.9g, 1.0g, 1.2g, 1.5g, 3g, 5g, 10g	P-2cm×2cm-2, P-2cm×2cm-4, P-3cm×25cm-2, P-3cm×25cm-4, P-5cm×5cm-4, P-5cm×5cm-8, P-5cm×5cm-12, P-8cm×8cm-4, P-8cm×8cm-8, P-8cm×8cm-12, P-8cm×8cm-16, P-8cm×8cm-24, P-9cm×10cm-4, P-9cm×10cm-8, P-9cm×10cm-12, P-9cm×10cm-16, P-9cm×10cm-24, P-10cm×15cm-4, P-10cm×15cm-8, P-10cm×15cm-12, P-10cm×15cm-16, P-10cm×15cm-24, P-12cm×12cm-4, P-12cm×12cm-8, P-12cm×12cm-12, P-12cm×12cm-16, P-12cm×12cm-24, P-15cm×15cm-4, P-15cm×15cm-8, P-15cm×15cm-12, P-15cm×15cm-16, P-15cm×15cm-24, P-20cm×20cm-4,	Analysis 2

		P-20cm×20cm-8, P-20cm×20cm-12, P-20cm×20cm-16, P-20cm×20cm-24, P-30cm×30cm-4, P-30cm×30cm-8, P-30cm×30cm-12, P-30cm×30cm-16, P-30cm×30cm-24; J-5cm×150cm, J-5cm×300cm, J-8cm×150cm, J-8cm×300cm, J-10cm×150cm, J-10cm×300cm; Z-5cm×150cm×4cm, Z-5cm×150cm×6cm, Z-5cm×150cm×8cm, Z-5cm×350cm×6cm, Z-5cm×350cm×8cm, Z-8cm×150cm×4cm, Z-8cm×150cm×6cm, Z-8cm×150cm×8cm, Z-8cm×150cm×10cm, Z-8cm×150cm×12cm, Z-8cm×350cm×4cm, Z-8cm×350cm×6cm, Z-8cm×350cm×8cm, Z-8cm×350cm×10cm, Z-8cm×350cm×12cm, Z-10cm×150cm×4cm, Z-10cm×150cm×6cm, Z-10cm×150cm×8cm, Z-10cm×150cm×10cm, Z-10cm×150cm×12cm, Z-10cm×350cm×4cm, Z-10cm×350cm×6cm, Z-10cm×350cm×8cm,	

		Z-10cm×350cm×10cm, Z-10cm×350cm×12cm; L-0.8cm×3.8cm, L-1cm×3.8cm, L-1.2cm×3.8cm, L-1.5cm×3.0cm, L-1.8cm×3.0cm, L-2cm×2.5cm	
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Pyrogen	No Pyrogen	No Pyrogen	Same
Sensitization	No Sensitization	No Sensitization	Same
Intracutaneous Reactivity	No Intracutaneous Reactivity	No Intracutaneous Reactivity	Same
Acute Systemic Toxicity	No Acute Systemic Toxicity	No Acute Systemic Toxicity	Same
Sterilization	Co60 Radiation sterilization	Co60 Radiation sterilization	Same
SAL	10^{-6}	10^{-6}	
Label and Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Analysis 1-Material

The hemostatic material of the proposed device is the same as the predicate device. The proposed device materials are cotton and Zeolite, and the predicate device materials are gauze and Zeolite. The gauze is also composed of cotton fiber.

Analysis 2-Size

The configuration of the subject device and the predicate device are different in representation; the subject device is shown in mass, whereas the predicate device is shown based on length, width, and height. The mass of the subject device is similar to the predicate device, and the amount of Zeolite is the same, ≥10% by weight.

8. Substantially Equivalent Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the proposed device in 510(k) submission, Zeolite Hemostatic Cotton, substantial equivalence to the device cleared under K211570, Zeolite Hemostatic Gauze.