Hangzhou Zeo-Innov Life Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

April 21, 2023

Re: K211570
Trade/Device Name: Zeolite Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: QSY

Dear Diana Hong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 10, 2022. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie 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

February 10, 2022

Hangzhou Zeo-Innov Life Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211570
Trade/Device Name: Zeolite Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 10, 2022
Received: January 11, 2022

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,

Julie A. Morabito -S

Julie 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 *K211570*

Device Name
Zeolite Hemostatic Gauze

Indications for Use *(Describe)*
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 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K211570

1. Date of Preparation: 02/08/2022

2. Sponsor Identification

Hangzhou Zeo-Innov Life Technology Co., Ltd.
R101, building 2, No.291, Fucheng Road, HEDA, Hangzhou, Zhejiang, 310018, China

Establishment Registration Number: Not yet registered

Contact Person: Lijuan Zhao
Position: Chief executive officer
Tel: +86- 571-86651470
Fax: +86- 571-86651470
Email: zhaolj@zeo-innov.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Zeolite Hemostatic Gauze
Common Name: Hemostatic Gauze

Regulatory Information
Product code: FRO
Classification Name: Dressing, Wound, Drug;
Classification: Unclassified;
Review Panel: General & Plastic Surgery;

Indication for Use:
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 wounds, minor cuts, and abrasions.

Device Description
The Zeolite Hemostatic Gauze consists of zeolite and gauze. Zeolite Hemostatic Gauze is provided in a sterile dressing format that conforms readily to the wound. It is available in four types, which are P (Sheet), J (Rolled), Z (Folded) and L (Cubed). The difference between each type is the dressing shape. Each type is available in a range of different sizes.

5. Identification of Predicate Device and Reference Device

Predicate device:
510(k) number: K072474
Product Name: QuikClot® eX™

Reference device:
510(k) number: K013390
Product Name: QuikClot

6. 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: 2015 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929: 2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ASTM F1980: 2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F3039: 2015 Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration;
- ASTM D3078-02 (Reapproved 2021)e1 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- 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: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

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 $\geq$300% and the hydration temperature rise is $\leq$1.0℃. The maximum exothermic temperature of the propose device is 0.5 ℃. The zeolite amount of the proposed device is $\geq$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-16), seal strength (ASTM F88/F88M-15), dye penetration test (ASTM F1929-15/F3039-15), vacuum leak (ASTM D3078-02(2013)) and packaging resistance bacteria performance (DIN 58953-6-2010). The test result showed that the device package can maintain its integrity.

Sterilization and shelf life testing listed in following table were performed on the proposed device. Endotoxin limit did not exceed 20EU/device. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

Bacteria Endotoxin Limit	USP <85>
Shelf Life Evaluation	Water absorption, zeolite content, and heat release, package tests were performed on aging samples 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,
- Irritation,
- Systemic toxicity,
- Pyrogen testing.

Animal Study

In the animal study conducted, 16 animals were selected for hemostatic testing, 8 for testing of the subject device, 8 for predicate device. A in vivo testing using pig as a model is conducted on the subject device and predicate device to supports the indications for use of the subject device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device K211570	Predicate Device K072474	Reference Device K013390	/
Product Code	FRO	FRO	FRO	Same
Class	Unclassified	Unclassified	Unclassified	Same
Indication for Use	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 wounds, minor cuts, and abrasions.	Prescription Use: QuikClot® eX™ is intended for temporary external use to control traumatic bleeding. Over-The-Counter Use: QuikClot® eX™ is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.	QuikClot is intended for emergency use only as an external temporary traumatic wound treatment to achieve hemostasis for moderate to severe bleeding.	Same
Material	Gauze Zeolite	Gauze Clay Mineral (Kaolin)	Zeolite	Analysis 1
Single Use	Yes	Yes	Yes	Same
Size	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,	4 in × 4 in	Unknown	Analysis 2

	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, 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			
Biocompatibility	No Cytotoxicity No intracutaneous reactivity No Sensitization No Acute Systemic Toxicity No pyrogen	Comply with ISO 10993 standards requirements	Comply with ISO 10993 standards requirements	Analysis 3
Sterilization	Co60 Radiation sterilization	Radiation sterilization	Unknown	Analysis 4
SAL	10^{-6}	10^{-6}	Unknown	
Label and Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Analysis 1- Material

The material for the proposed device is different from the predicate device. The proposed device material is gauze and zeolite, the predicate device material is gauze and clay mineral (Kaolin). Zeolite is also a kind of clay mineral, which is similar to Kaolin.

Analysis 2- Size

The size for the proposed device is different from the predicate device. Different size can be selected by different condition.With respect to materials, the subject device demonstrates substantial equivalence to the predicate device.

Analysis 3- Biocompatibility

The biocompatibility test were performance on the predicate device. The contact level of the proposed device is breached or compromised surfaces, and the contact duration is limited contact (≤24 hours). So, the proposed device has been tested for cytotoxicity, sensitization, irritation, systemic toxicity, pyrogen testing. The results for the biocompatibility testing showed that the proposed device is biocompatible. With respect to materials, the subject device demonstrates substantial equivalence to the predicate device.

Analysis 4-Sterilization and SAL

The sterilization method of the predicate device and the proposed device both are radiation sterilization. The proposed device is radiation sterilization of Co60, while the radiation sterilization type of the predicate device is unknown. However, the performance testing of the proposed device has been conducted on the final product and the test results show that the proposed device meets the acceptance criteria.

9. Substantially Equivalent (SE) Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission, Zeolite Hemostatic Gauze, demonstrates substantial equivalence to the device cleared under K072474.