



October 18, 2022

MEBO Life Science Inc.
% Wei Hsu
Regulatory Manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong
China

Re: K222657
Trade/Device Name: MEBO Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 21, 2022
Received: September 22, 2022

Dear Wei Hsu:

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 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

Indications for Use

510(k) Number (if known)
K222657

Device Name
MEBO Wound Dressing

Indications for Use (Describe)

Rx Indications for Use:

For professional use, MEBO Wound Dressing is indicated for management of the following types of wound:

- Skin graft recipient sites
- Newly sutured wounds
- Lacerations and abrasions
- Minor or superficial-partial thickness burns

OTC Indications for Use:

For over-the-counter use, MEBO Wound Dressing is indicated for:

- Minor cuts
- Minor abrasions
- Minor lacerations
- Minor burns

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

1 Date Prepared

Sep 22nd, 2022

2 Submitter's Information

Name of Sponsor: MEBO Life Science Inc.

Address: 325 North Puente Street # A Brea, CA92821, USA.

Contact Name: Guoxin Tao

Contact e-mail: taoguoxin@hotmail.com

Telephone No.: (626)617-5110

3 Trade Name, Common Name, Classification

Trade/Device Name: MEBO Wound Dressing

Classification name: Dressing, Wound, Drug

Product code: FRO

Device Class: Unclassified

4 Identification of Predicate Device /Reference Device

K193439 MEBO Wound Dressing

5 Description of the Device

The MEBO Wound Dressing is a electron beam irradiation sterilized dressing consisting of sesame oil, beeswax and fabric dressing, which provides a moist environment for wound healing.

6 Indication

For professional use, MEBO Wound Dressing is indicated for management of the following types of wound:

- Skin graft recipient sites
- Newly sutured wounds
- Lacerations and abrasions
- Minor or superficial-partial thickness burns

For over-the-counter use, MEBO Wound Dressing is indicated for:

- Minor cuts

- Minor abrasions
- Minor lacerations
- Minor burns

7 Similarities and Differences of the Proposed Devices to the Predicate Device/Reference Device

MEBO Wound Dressing described in this premarket notification is compared with the Predicate Device in terms of indication, mechanism, delivery system, structure/material, applied duration, and sterilization method.

The following table shows similarities and differences between our device and the predicate device/reference device.

	Subject Device	Predicate Device	Similarities and Differences
Manufacturer	MEBO Life Science Inc.	MEBO Life Science Inc.	
Trade Name	MEBO Wound Dressing	MEBO Wound Dressing	
510(k) number	NA	K193439	--
Device Class	Unclassified	Unclassified	Same
Product Code	FRO	FRO	Same
Device classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Same
Regulation number	NA	NA	Same
Indications for Use (Rx)	Indicated for management of the following types of wound: <ul style="list-style-type: none"> - Skin graft recipient sites -Newly sutured wounds -Lacerations and abrasions 	Indicated for management of the following types of wound: <ul style="list-style-type: none"> - Skin graft recipient sites -Newly sutured wounds -Lacerations and abrasions 	Same

	-Minor or superficial-partial thickness burns	-Minor or superficial-partial thickness burns	
Indications for Use (OTC)	Indicated for -Minor cuts -Minor abrasions -Minor lacerations -Minor burns	N/A	Different Subject device has additional OTC Use with narrowed indication range of predicate device.
Mechanism	Provides a moist environment for optimal wound healing	Provides a moist environment for optimal wound healing	Same
Delivery System	Dressing	Dressing	Same
Applied Duration	The maximum contact duration time of each piece of dressing does not exceed 24h, and the cumulative duration time of contacting with wounds shouldn't exceed 30 days.	The maximum contact duration time of each piece of dressing does not exceed 24h, and the cumulative duration time of contacting with wounds shouldn't exceed 30 days.	Same
Structure/Material	Non-woven fabric (50% polyester and 50% viscose) immersed with a mixture of sesame oil and beeswax.	Non-woven fabric (50% polyester and 50% viscose) immersed with a mixture of sesame oil and beeswax.	Same
Biocompatibility	Biocompatibility established	Biocompatibility established	Same
Single use	Yes	Yes	Same
Sterilization	Electron beam irradiation	Gamma irradiation	Different

			Both are sterilized to SAL 10^{-6} level. The sterilization of subject device is validated per ANSI AAMI ISO 11137-1: 2006/ (R)2015.
	SAL: 10^{-6}	SAL: 10^{-6}	Same

The MEBO Wound Dressing has same mechanism, material, product design, applied duration as the predicate device.

The differences above between the subject device and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

8 Performance Testing Summary

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Appearance
- Size deviation
- Liquid absorbency
- Acid Value
- Paste content (The mass of sesame oil and beeswax mix in the non-woven fabrics)
- β -Sitosterol content
- Endotoxin level
- Biocompatibility
 - a. ISO 10993-1:2009 - Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
 - b. ISO 10993-5:2009 - Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity

- c. ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- c. ISO 10993-10:2010 - Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization
- d. ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity-Acute and Subchronic systemic toxicity
- e. USP41-NF36<151> Pyrogen test
- f. USP42 <161> Medical device-Bacterial Endotoxin Test

9 Conclusion

Based on the information provided within this 510(k) submission, MEBO Life Science Inc. concludes that the proposed MEBO Wound Dressing is substantially equivalent to the predicate device listed and is as safe, as effective and performs as well as the legally marketed predicate device.