September 4, 2020

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

Re: K193439
Trade/Device Name: MEBO Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 29, 2019
Received: August 4, 2020

Dear Wei-Shan 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193439

Device Name
MEBO Wound Dressing

Indications for Use *(Describe)*
The 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

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

1 Date Prepared

Sep 4th, 2020

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

Primary Predicate Device: K181478 Roosin Xeroform Petrolatum Dressing

Reference Device: K052643 EPICERAM® Skin Barrier Emulsion

5 Description of the Device

The MEBO Wound Dressing is a CO^{60} gamma-radiation sterilized dressing consisting of sesame oil, beeswax and fabric dressing, which provides a moist environment for wound healing.

6 Indication

The 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

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 following Predicate Device and Reference Device in terms of indication, mechanism, delivery system, structure/material, applied duration, and sterilization method.

(1) Primary Predicate Device: K181478 Roosin Xeroform Petrolatum Dressing

(2) Reference Device: K052643 EPICERAM® Skin Barrier Emulsion

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

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Similarities and Differences**
Manufacturer	MEBO Life Science Inc.	Roosin Medical Co., Ltd.	CERAGENIX CORPORATION	
Trade Name	MEBO Wound Dressing	Roosin Xeroform Petrolatum Dressing	EPICERAM® Skin Barrier Emulsion	
510(k) number	K193439	K181478	K052643	--
Device Class	Unclassified	Unclassified	Unclassified	Same
Product Code	FRO	FRO	FRO	Same
Device classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Same
Regulation number	NA	NA	NA	Same
Indications for Use	The 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	Roosin Xeroform Petrolatum Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be	EpiCeram is a Skin Barrier Emulsion to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact	Same as primary predicate. Different from reference device. Reference devic provides a moist wound environment which is the same mechanism as the subject device.

	thickness burns	used as an initial layer in dressing surgical wounds with light exudate.	dermatitis, radiation dermatitis. EpiCeram helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Apply Epiceram a thin layer to affected skin area 2 times per day and massage gently into the skin. If the skin is broken, cover Epiceram with a dressing of choice.	
Mechanism	Provides a moist environment for optimal wound healing	Maintains a moist wound environment	Maintain a moist wound and skin environment.	Same
Delivery System	Dressing	Dressing	Topical Emulsion	Same as primary predicate. Different from reference device.
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.	This product should not be used for more than 7 days at most, and should not be used for more than 30 days.	Apply twice daily or as indicated by the radiation therapist. If condition does not improve within 10 to 14 days, consult a physician.	Similar to primary predicate and reference device.
Structure/Material	Non-woven fabric (50% polyester and 50% viscose) immersed with a mixture of sesame oil and beeswax.	Cotton Gauze, 3% Bismuth Tribromophenate, and Petrolatum	Capric Acid, Cholesterol, Citric Acid, Conjugated Linoleic Acid, Dimethicone, Disodium EDTA, **E. Cerifera (Candelilla)**	Different from primary predicate in material, but similar design feature. Reference device contains one similar

			Wax, Food Starch, Modified Corn Syrup Solids, Glycerin, Glyceryl Stearate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Potassium Hydroxide, Purified Water, Sorbic Acid, Squalane, Xanthan Gum.	component, Candelilla Wax, to beeswax in the subject device. The main component of both beeswax and Candelilla Wax is triacontanyl palmitate.
Biocompatibility	Biocompatibility established	Biocompatibility established	Biocompatibility established	Same
Single use	Yes	Yes	N/A	Same as primary predicate. Different from reference device.
Sterilization	Gamma, Sterile to 10^{-6} SAL	Gamma, Sterile to 10^{-6} SAL	Non-sterile	Same as primary predicate. Different from reference device.

The MEBO Wound Dressing has same indications, same mechanism, same sterilization method, similar product design, similar applied duration as the predicate device, and has similar material as the reference device. The differences above between the subject device and predicate device/reference device do not affect the basic design principle, usage of the subject device.

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 does not raise different questions of safety or effectiveness.