March 27, 2023

M/s. Meril Endo Surgery Private Limited
Umesh Sharma
General Manager - Quality Assurance/Regulatory Affairs
Third Floor, E1-E3, Meril Park
Survey No, 135/2/B and 174/2, Muktanand Marg,
Chala, Vapi – 396191 Gujarat, India

Re: K200452
Trade/Device Name: MERIL-BONEWAX™
Regulatory Class: Unclassified
Product Code: MTJ
Dated: February 28, 2023
Received: March 6, 2023

Dear Umesh Sharma:

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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K200452

Device Name
MERIL - BONEWAX™

Indications for Use *(Describe)*
MERIL - BONEWAX™ is intended to be used in the control of bleeding from bone surfaces during surgical operations.

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.

Endo Surgery

510 (k) Summary

510(k) Number:K200452

I. Submitter

M/s. Meril Endo Surgery Private Limited
Third Floor, E1 – E3, Meril Park,
Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi – 396191 Gujarat, India.

Tel. No: +91-260-3052100, Fax: +91-260-3052125
Contact Person: Umesh Sharma
E-mail: umesh.sharma@merillife.com
Web site: www.merillife.com

Date Prepared: March 23rd, 2023

II. Device

Trade Name	MERIL - BONEWAX™
Panel	Orthopaedics
Common/ Usual Name	Sterilized Bone Wax
Classification Name	Wax, Bone
Classification	Unclassified
Product Code	MTJ

III. Predicate Device

Subject device	**Predicate device**		
	Trade Name	**Manufacturer**	**510 (K) No.**
Meril-Bone Wax™	CP Medical Bone Wax **(Primary Predicate Device)**	CP Medical Inc.	K024372
	Sharpoint Lukens" Bone Wax	Surgical Specialities Corporation	K050292

IV. Device Description

MERIL - BONE WAX™ is ivory white, intended to aid mechanically in the control of bleeding of bone injuries, whether attributable to trauma or surgical intervention. It is composed of refined beeswax with Iso propyl myristate added as softening agent, and is supplied sterile in thin sheets. It is opaque and has a waxy odor.

It is available as 2 or 2.5gm bone wax per pack.

MERIL - BONE WAX™ achieves local hemostasis of bone by acting as a mechanical (tamponade) barrier. It does not act biochemically and is non-absorbable.

V. Intended Use

MERIL - BONEWAX™ is intended to be used in the control of bleeding from bone surfaces during surgical operations.

VI. Substantial Equivalence

The MERIL – BONE WAX™ is substantially equivalent to marketed predicate devices with respect to intended use and physical characteristics. The MERIL – BONE WAX™ has the same mechanism of action as predicate devices.

The safety and effectiveness of MERIL – BONE WAX™ has been evaluated for the following performance and safety requirements.

1. Intended Use
2. Material composition
3. Mechanism of action
4. Physical Characteristics
5. Single use
6. Sterilization
7. Packaging
8. Biocompatibility

VII. Preclinical Data

Performance Tests

Bench testing was conducted on MERIL – BONE WAX™ test like kneadability and spreadability tests were conducted to demonstrate device usability, and an animal performance test in a porcine model were performed using the MERIL – BONE WAX™ to demonstrate that the subject device was effective in control of bleeding from the bone surface.

Biocompatibility

The biocompatibility evaluation for MERIL – BONE WAX™ was conducted in accordance with Guidance document 'Use of International Standard ISO 10993-1, ''Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'' September 4, 2020 and International Standards ISO 10993-1 "Biological evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" as recognized by FDA.

The test results suggest that the subject device is biocompatible.

Sterilisation

MERIL – BONE WAX™ is sterilized by Gamma irradiation. Method followed for sterilization by gamma irradiation is as per ISO 11137-1:2006 (Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices) and ISO 11137-2: 2013 (Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose).

Bacterial Endotoxin Testing

To evaluate the Bacterial Endotoxin for MERIL – BONE WAX™, the Limulas *Limulus* amebocyte lysate (LAL) test was conducted by Gel Clot Technique

and found that the test results met the specification of < 20 EU/Device in accordance with ANSI/AAMI ST72:2019.

Packaging & Shelf life

Following packaging and shelf life study was conducted to ensure package integrity throughout the shelf life.

- Packaging validation as per ISO 11607
- Shelf life validation as per ICH Q1A (R2) & ISO 11607
- Transportation Study as per ASTM D 999 & ASTM D 5276

VIII. Conclusion

MERIL – BONE WAX™ is substantially equivalent to currently marketed devices and presents no substantial differences in composition, intended use and function to predicate device.

The performance, biocompatibility, sterilization, packaging and shelf life study conducted on MERIL – BONE WAX™ demonstrated the device is as safe and as effective as the predicate device. Hence, MERIL – BONE WAX™ will perform as intended in the specified use conditions.