November 23, 2020

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 & 174/2,
Muktanand Marg
Chala, Vapi, 396191 In

Re: K200166
Trade/Device Name: Mirus Ligating Clip, Mirus Ligating Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Ligating clip
Regulatory Class: Class II
Product Code: FZP
Dated: October 14, 2020
Received: October 20, 2020

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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K200166

Device Name
Mirus™ Ligating Clip

Indications for Use *(Describe)*
The Mirus™ Ligating clip is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with size of the clip.

Mirus™ Ligating Clip applier is intended to apply ligating clips on tubular structures or vessels wherever a metal ligating clip is indicated.

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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Meril
Endo Surgery

510(k) Summary

I. Submitter

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Web site: www.merillife.com
E-mail: umesh.sharma@merillife.com

Contact Person: Umesh Sharma
Date Prepared: November 10th, 2020

II. Device

Trade Name	Mirus™ Ligating Clip & Clip Applier	
Panel	General and Plastic Surgery	
Common/ Usual Name	Ligating clip	Clip Applier
Classification Name	Clip Implantable	Manual surgical instrument for general use
Regulation Number	21 CFR 878.4300	21 CER 878.4800
Classification	Class II	Class I
Product Code	FZP	GAG

III. Predicate Device

K834267: Ligaclip™ Titanium Ligating Clip, Ethicon, Inc.(Primary Predicate Device)
K982313: Horizon™ Titanium Clips, Weck Closure Systems

IV. Device Description

Mirus™ Ligating clip are sterile, single use, implantable device made of implant grade titanium (ISO 5832-2 / ASTM F 67). The clips are available in various sizes with 6 clips packed in a single plastic cartridge.

Mirus™ Ligating clips are supplied with multiuse non sterile stainless steel Mirus™ Ligating Clip applier, allows the end user to ligate a wide range of vessels and tissue structures using the ligating clips

V. Intended Use

The Mirus™ Ligating clip is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with size of the clip.

Mirus™ Ligating Clip applier is intended to apply ligating clips on tubular structures or vessels wherever a metal ligating clip is indicated.

VI. Substantial Equivalence

The device design, material of construction, performance, packaging and intended uses are similar to the predicate device. Substantial equivalence is conducted based on the following parameters:

1. Intended use
2. Device Size
3. Principle of Operation
4. Single use
5. Sterilisation method
6. Packaging & Labelling
7. Performance

Endo Surgery

VII. Performance Data

Mirus™ Ligating Clip was subjected to the performance testing. The safety and effectiveness of Mirus™ Ligating Clip has been evaluated for the following performance and safety requirements.

1. Dimension compliance
2. Shape
3. Radial pull off force
4. Axial Pull off force
5. Leakage
6. Applier Performance
7. Biocompatibility
    a. In Vitro Cytotoxicity Study
    b. Skin Sensitization Study
    c. Intracutaneous Reactivity Test
    d. Acute Systemic Toxicity Study
    e. Sub Acute Systemic Toxicity
    f. Intramuscular Implantation Test
    g. Bacterial Reverse Mutation Test
    h. In Vitro Hemolysis Test
    i. Material Mediated Pyrogen Test

VIII. Conclusion

Mirus™ Ligating Clips are composed of implant grade Titanium. Also Mirus™ Ligating Clips have the same intended use and the same basic technology as that of the predicate devices. Meril's device is substantially equivalent to the predicate in term of material, features and design and it does not pose any new issues concerning safety and effectiveness.