February 5, 2021

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 Gujarat, India

Re: K200320
Trade/Device Name: Mirus Circular Stapler, Mirus Linear Cutter and Reload, Mirus Hemorrhoidal Circular Stapler, Mirus Linear Stapler and Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 2, 2021
Received: January 7, 2021

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,

For 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200320

Device Name
Mirus™ Circular Stapler, Mirus™ Linear Cutter and Reload, Mirus™ Hemorrhoidal Circular Stapler, Mirus™ Linear Stapler and Reload.

Indications for Use *(Describe)*

Mirus™ Circular Stapler has application throughout the alimentary tract for end to end, end to side and side to side anastomoses.

Mirus™ Linear Cutter and Reload have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses.

Mirus™ Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

Mirus™ Linear Stapler and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures.

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

I. Submitter

M/s. Meril Endo Surgery Private Limited
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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: February 5th, 2021

II. Device

Trade Name	**Mirus™ Family of Surgical Staplers** • Mirus™ Circular Stapler • Mirus™ Linear Cutter and Reload • Mirus™ Hemorrhoidal Circular Stapler • Mirus™ Linear Stapler and Reload	
Panel	General and Plastic Surgery	
Common/ Usual Name	Reload	Stapler
Classification Name	Implantable Staple	Stapler, surgical
Regulation Number	21 CFR 878.4750	21 CFR 878.4800
Classification	Class II	Class I
Product Code	GDW	GAG

510 (k) Summary

III. Predicate Device

Subject device	Predicate device		
	Trade Name	Manufacturer	510 (K) No.
Mirus™ Circular Stapler	Single Use Circular Stapler	Golden Stapler Surgical Co., Ltd.	K162707
Mirus™ Linear Cutter and Reload	Single Patient Use Linear Cutter and Reload		
Mirus™ Hemorrhoidal Circular Stapler	Single Use Hemorrhoidal Circular Stapler		
Mirus™ Linear Stapler and Reload	Single Patient Use Linear Stapler and Reload		

IV. Device Description

1. The Mirus™ Circular Stapler

The Mirus™ Circular Stapler are sterile, single use devices that simultaneously staple and cut tissue to create an anastomosis. The devices deliver double staggered concentric rows of staples on the outside of the cut line. The circular stapler is available in diameter of the staple line from 24mm, 25mm, 26mm, 29mm, 32mm or 34mm stapler. The device has a detachable anvil that allows the surgeon to place the anvil in the desired location. Mirus™ Circular Stapler is preloaded with Staples.

2. Mirus™ Linear Cutter and reload

Mirus™ Linear Cutter stapler and the Reload have two groups of staple lines in the target area, both of which are composed of a double row of titanium staples interlaced with each other and automatically cut the tissues between the two groups of staple lines when suturing. There are three suturing lengths of 60mm, 80mm and 100mm. The cartridge/ reload for Mirus™ Linear Cutter are supplied separately.

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3. Mirus™ Hemorrhoidal Circular Stapler

Mirus™ Hemorrhoids Circular Stapler is a set of instruments that places a circular row of titanium staples (double staggered) while simultaneously resecting a segment of compressed soft tissue. The set is commonly used in the Procedure for Prolapse and Hemorrhoids (PPH). The set is also used for other applications where circular or semicircular stapling of anorectal tissue is desired. The Mirus™ Hemorrhoid circular stapler is preloaded with staples.

4. Mirus™ Linear Stapler and reload

Mirus™ Linear Stapler places a double staggered row of titanium Staples. They are available in 30mm, 45mm, 60mm and 90mm staple line length. The cartridge/ reload for Mirus™ Linear stapler are supplied separately

V. Intended Use

1. **Mirus™ Circular Stapler** has application throughout the alimentary tract for end to end, end to side and side to side anastomoses.

2. **Mirus™ Linear Cutter** and Reload have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses.

3. **Mirus™ Hemorrhoidal Circular Stapler** has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

4. **Mirus™ Linear Stapler** and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures.

510 (k) Summary

VI. Substantial Equivalence

The Mirus™ family of Surgical Staplers is substantially equivalent to marketed predicate devices with respect to intended use and technological characteristics. The Mirus™ family of Surgical Staplers operates on the same principle as predicate devices. The results demonstrated that the subject devices are as safe and as effective as the predicates.

1. Intended Use
2. Principle of Operation
3. Product design
4. Sterilization
5. Packaging
6. Safety Mechanism
7. Biocompatibility

VII. Preclinical Data

The following performance data were provided in support of the substantial equivalence determination.

Performance Tests

Simulated use testing was performed utilizing each device of the Mirus™ family of surgical staplers. The following testing demonstrated that subject devices substantially equivalent to the predicates.

- Visual Inspection
- Dimensional Measurement
- Open Staple Height
- Closed Staple Height
- Staple Formation Test
- Staple Line Integrity and Staple Formation
- Pressure Resistance Test
- Force to fire

510 (k) Summary

Biocompatibility

The biocompatibility evaluation for Mirus™ Family of Surgical Staplers was conducted in accordance with FDA Biocompatibility Guidance Document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 2016 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.

Based on attachment A (Table A.1) of the FDA guidance, following tests were identified and performed

- In vitro cytotoxicity test
- Skin sensitization test
- Intracutaneous reactivity test
- Acute systemic toxicity test
- Material mediated pyrogen test
- Hemolysis test
- Genotoxicity test
- Subchronic systemic toxicity test
- Intramuscular implantation test

Sterilisation

Mirus™ Family of Surgical Staplers are sterilized by Ethylene Oxide (EtO). The Ethylene oxide sterilization process is validated as per ISO 11135. The method used for ethylene oxide sterilization validation was overkill (half-cycle approach) method in a fixed chamber. Ethylene oxide residuals were tested and met ISO 10993-7 requirements.

The sterilization processes have demonstrated a sterility assurance level of 10^{-6}

510 (k) Summary

Packaging & Shelf life

The 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
- Performance testing on aged sample (Stability testing).
- Transportation Study as per ASTM D 999 & ASTM D 5276

VIII. Conclusion

Mirus™ family of surgical staplers is substantially equivalent to currently marketed devices and presents no substantial differences in design, intended use, function and technological characteristics to predicate device.

The performance, biocompatibility, sterilization, packaging and shelf life study conducted on Mirus™ family of surgical staplers demonstrated its safety and performance as predicate device.

Hence, Mirus™ family of surgical staplers will perform as intended in the specified use conditions.