February 1, 2018

M/s. Meril Endo Surgery Private Limited
Mr. Umesh Sharma
Deputy General Manager - Quality Assurance
Third Floor, E1-E3, Meril Park
Survey No. 135/2/B & 174/2, Muktanand Marg
Chala, Vapi District, Valsad, 396191 India

Re: K172146
Trade/Device Name: Meristeel
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless Steel Suture
Regulatory Class: Class II
Product Code: GAQ
Dated: December 29, 2017
Received: January 3, 2018

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172146

Device Name
MERISTEEL

Indications for Use *(Describe)*
MERISTEEL™ sutures are intended for use in abdominal wounds closure, hernia repair, sterna closure and orthopaedic procedure including cerclage & tendon repair.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Contact Person: Umesh Sharma
Date Prepared: June 21, 2017

II. Device

Sr. No.	Trade / Proprietary Name	Common Name	Classification	Regulatory Class	Product Code	Regulation Number	Review Panel
1.	**Meristeel™** - Stainless Steel Surgical Suture	Stainless Steel Surgical Suture, Non-Absorbable	Stainless Steel Surgical Suture, Non-Absorbable	II	GAQ	21 CFR 878.4495	General & Plastic Surgery Devices Panel

III. Predicate Device

Stainless Steel surgical suture (CP Medical) - (510k : K030351)

IV. Device Description

MERISTEEL™ Stainless steel suture is a monofilament, non-absorbable sterile surgical suture composed of stainless steel.
This suture is available undyed and uncoated.
MERISTEEL™ suture is available in a range of gauge sizes and lengths, and attached to standard stainless steel needles of various types and sizes.
Stainless steel suture complies with the requirements of the United States Pharmacopoeia for Non Absorbable Surgical suture and European Pharmacopoeia for Sterile Non-Absorbable surgical strands

V. Intended Use

MERISTEEL™ sutures are intended for use in abdominal wounds closure, hernia repair, sterna closure and orthopaedic procedure including cerclage & tendon repair.

VI. Substantial Equivalence

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

1. Product description
2. Intended use
3. Suture Size
4. Single use
5. Sterilisation method

6. Packaging
7. Label Claim
8. Performance
    a. Diameter USP <861>
    b. Tensile strength USP <881>
    c. Needle attachment USP <871>
    d. Suture Length
9. Labelling and Instructions for use (IFU)

VII. Performance Data

The Surgical Suture was subjected to the performance testing as per USP requirements. The safety and effectiveness of the Surgical Suture has been evaluated for the following performance and safety requirements.

1. Diameter USP <861>
2. Tensile strength USP <881>
3. Needle attachment USP <871>
4. Suture Length
5. Biocompatibility as per ISO 10993-1

VIII. Conclusion

Meristeel™ Stainless Steel Sutures are substantially equivalent to currently marketed devices Stainless Steel surgical suture (CP Medical) - (510k: K030351) and present no substantial differences in design, material, intended use and function to predicate device.