Food and Drug Administration
10903 New Hampshire Avenue
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September 28, 2017

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, India, Valsad
Gujarat, 396191, IN

Re: K172659
Trade/Device Name: MEGASORB - Natural absorbable Polyglycolic Acid Surgical Suture, MITSU - Absorbable Polyglactin 910 Surgical Sutures, MITSU FST - Absorbable Polyglactin 910 Surgical Suture, FILAXYN - Absorbable Polydioxanone Surgical (PDS), FILAPRON - Absorbable poly(glycolide-co-caprolactone) Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, NEW
Dated: August 28, 2017
Received: September 5, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K172659

Device Name
MEGASORB, MITSU, MITSU FST, FILAXYN, FILAPRON

Indications for Use *(Describe)*
MEGASORB Absorbable Polyglycolic Acid Surgical Sutures are indicated for use in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological procedures.

MITSU suture is intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

MITSU FST suture is indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. MITSU FST suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

FILAXYN sutures are indicated for use in soft tissue approximation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

FILAPRON dyed / undyed sutures are intended for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

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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# 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: August 26, 2017

## II. Device

| Sr. No. | Trade / Proprietary Name | Common Name | Regulatory Class | Product Code | Regulation Number | Review Panel |
|---|---|---|---|---|---|---|
| 1. | **MEGASORB™** absorbable Polyglycolic Acid Surgical Suture | Braided coated Polyglycolic Acid Suture | II | GAM | 878.4493 | General & Plastic Surgery |
| 2. | **MITSU™** Absorbable poly(glycolide/l-lactide) Surgical Sutures | Braided coated Polyglactin Suture | II | GAM | 878.4493 | General & Plastic Surgery |
| 3. | **MITSU FST™** Absorbable poly (glycolide / l-lactide) Surgical Sutures | Braided coated Polyglactin Suture | II | GAM | 878.4493 | General & Plastic Surgery |
| 4. | **FILAXYN™** Absorbable poly (p-dioxanone) Surgical Suture | Monofilament Polydioxanone Suture | II | NEW | 878.4840 | General & Plastic Surgery |
| 5. | **FILAPRON™** Absorbable poly (glycolide –co - caprolactone) Surgical Suture | Monofilament Polyglecaprone Suture | II | GAM | 878.4493 | General & Plastic Surgery |

## III. Predicate Device

| Sr. No. | Meril's Suture Trade / Proprietary Name | Predicate Device Name | Predicate Device 510(k) No. |
|---|---|---|---|
| 1. | **MEGASORB™** absorbable Polyglycolic Acid Surgical Suture | MEGASORB™ | K150717 |
| 2. | **MITSU™** Absorbable poly(glycolide/l-lactide) Surgical Sutures | MITSU™ | K150717 |
| 3. | **MITSU FST™** Absorbable poly(glycolide/l-lactide) Surgical Sutures | MITSU FST™ | K150717 |
| 4. | **FILAXYN™** Absorbable poly (p-dioxanone) Surgical Suture | FILAPRON™ | K150717 |
| 5. | **FILAPRON™** Absorbable poly(glycolide-co-caprolactone) Surgical Suture | FILAXYN™ | K150717 |

## IV. Device Description

### A. MEGASORB™ absorbable Polyglycolic Acid Surgical Suture

MEGASORB™ suture is a synthetic absorbable sterile surgical suture composed of Polyglycolic Acid. Braided MEGASORB™ sutures are coated with polycaprolactone and calcium stearate. Poly Glycolic Acid coated with polycaprolactone and calcium stearate has been found to be non-pyrogenic and eliciting only slight tissue reaction during absorption. The empirical formula of the Polyglycolic Acid, polycaprolactone and calcium stearate is $(C_2H_2O_2)_n$, $(C_6H_{10}O_2)_n$ and $C_{36}H_{70}O_4Ca$ respectively.MEGASORB™ sutures are available either undyed or dyed (D and C Violet No. 2, Colour Index number: 60725) form. MEGASORB™ is available in a range of gauge sizes and lengths, attached to standard stainless steel needles of varying types and sizes.

MEGASORB™ suture is available in U.S.P. size range 8-0 to 2, undyed/dyed form in pack size of 6/12/24/36.

**B. MITSU™ Absorbable poly(glycolide/l-lactide) Surgical Sutures**

MITSU™ is a braided coated synthetic absorbable sterile poly(glycolide/l-lactide) surgical suture. It is composed of a copolymer made of glycolide and L-lactide. MITSU™ sutures are coated with a mixture containing equal parts of copolymer of glycolide and lactide and calcium stearate. The empirical formula of the copolymer is $(C_2H_2O_2)_m$ $(C_3H_4O_2)_n$ and calcium stearate is $C_{36}H_{70}O_4Ca$. Poly(glycolide/l-lactide) copolymer and poly(glycolide/l-lactide) with calcium stearate exhibit non-pyrogenic properties. MITSU™ sutures are available in undyed and dyed (D and C violet No. 2, Colour Index No. 60725) form. Available in a broad range of suture sizes and lengths, MITSU™ comes with standard stainless steel needles of varying types and sizes.

MITSU™ suture is available in size range 8-0 to 2, undyed/dyed form, and pack size of 6/12/24/36.

**C. MITSU FST™ Absorbable poly(glycolide/l-lactide) Surgical Sutures**

MITSU FST™ is a braided coated synthetic absorbable sterile poly(glycolide/l-lactide) surgical suture. It is composed of a copolymer made from glycolide and L-lactide. MITSU FST™ sutures are coated with a mixture containing equal parts of copolymer of glycolide and lactide and calcium stearate. The empirical formula of the copolymer is $(C_2H_2O_2)_m$ $(C_3H_4O_2)_n$ and calcium stearate is $C_{36}H_{70}O_4Ca$. The rapid loss of strength is achieved by using polymer material with lower molecular weight than that of regular MITSU™ suture. Poly(glycolide/l-lactide) copolymer and poly(glycolide/l-lactide) with calcium stearate exhibit non-pyrogenic properties and elicit only slight tissue reaction during absorption. MITSU FST™ sutures are available in undyed form. Available in a broad range of suture sizes and lengths, MITSU FST™ comes with standard stainless steel needles of varying types and sizes.

MITSU FST™ suture is available in U.S.P. size range 6-0 to 1, undyed form in pack size of 6/12/24/36.

**D. FILAXYN™ Absorbable poly (p-dioxanone) Surgical Suture**

FILAXYN™ is a sterile synthetic absorbable monofilament suture composed of Poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Poly (p-dioxanone) polymer has non-pyrogenic properties. FILAXYN™ sutures are available in undyed or dyed (D and C Violet No.2, Color Index number: 60725) form. FILAXYN™ is available in a range of gauge sizes and lengths, attached to standard stainless steel needles of varying types and sizes.

FILAXYN™ suture is available in size range 7-0 to 2, undyed/dyed form in pack size of 6/12/24/36.

**E. FILAPRON™ Absorbable poly(glycolide-co-caprolactone) Surgical Suture**

FILAPRON™ is a sterile synthetic absorbable monofilament suture is composed of poly(glycolide-co-caprolactone). The empirical molecular formula of the polymer is $(C_2H_2O_2)_m$ $(C_6H_{10}O_2)_n$ poly(glycolide-co-caprolactone) has non-pyrogenic properties. FILAPRON™ sutures are available either in undyed or dyed (D and C violet No. 2, Colour Index No. 60725) form. FILAPRON™ is available in a range of gauge sizes and lengths and attached to standard stainless steel needles of varying types and sizes.

FILAPRON™ suture is available in size range 6-0 to 2, undyed/dyed form in pack size of 6/12/24/36.

## V. Intended Use

1. **MEGASORB™** Absorbable Polyglycolic Acid Surgical Sutures are indicated for use in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological procedures.

2. **MITSU™** suture is intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

3. **MITSU FST™** suture is indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. MITSU FST™ suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

4. **FILAXYN™** sutures are indicated for use in soft tissue approximation, including use in ophthalmic procedures, but not for use in cardio vascular and neurological procedures.

5. **FILAPRON™** dyed / undyed sutures are intended for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

## 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. Product description
2. Intended use
3. Suture Size
4. Colorant Used
5. Suture Coating
6. Single use
7. Sterilisation method
8. Packaging
9. Label Claim
10. Performance
    a. Diameter USP <861>
    b. Tensile strength USP <88I>
    c. Needle attachment USP <871>
    d. Resorption profile
    e. Suture Length
11. 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 <88I>
3. Needle attachment USP <871>
4. Resorption Profile
5. Suture Length
6. Biocompatibility
    a. In Vitro Cytotoxicity Study

b. Skin Sensitization Study
c. Intracutaneous Reactivity Test
d. Acute Systemic Toxicity Study
e. Sub Chronic Toxicity Study
f. Intramuscular Implantation Test
g. Bacterial Reverse Mutation Test
h. Mammalian Erythrocyte Micronucleus Test
i. In Vitro Hemolysis Test
j. Pyrogen Test

## VIII. Conclusion

Meril's Absorbable surgical Sutures are composed of the same materials, as are the predicate devices and has the same design, as do the predicate.