DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

M/S. Meril Endo Surgery Private Limited
Mr. Umesh Sharma
Deputy General Manager - Quality Assurance
3fl, E1-e3, Meril Park, Survey No. 135/2/b & 174/2,
Muktanand Marg
Chala, Vapi, Gujaret 396191
INDIA

Re: K160623
Trade/Device Name: Filasilk - Natural Non-absorbable Silk Surgical Suture, Filamide - Non Absorbable Polyamide Surgical Sutures, Mericron Xl - Non Absorbable Polyester Surgical Suture, Filaprop - Non Absorbable Polypropylene Surgical Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP, GAR, GAT, GAW
Dated: March 1, 2016
Received: March 4, 2016

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 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 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 yours,

Jennifer R. Stevenson -A

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)

K160623

Device Name
FILAMIDE

Indications for Use (Describe)
FILAMIDE is intended for use as non-absorbable sutures in general soft tissue approximation including skin tissue closure and/or ligation in cardiac, vascular and ophthalmic 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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510(k) Number (if known)

K160623

Device Name
FILAPROP

Indications for Use (Describe)
FILAPROP sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological 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)

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510(k) Number (if known)

K160623

Device Name
FILASILK

Indications for Use (Describe)
FILASILK is intended for use as non-absorbable sutures in general soft tissue approximation and/or ligation including use in cardiac, vascular and ophthalmic 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K160623

Device Name
MERICRON XL

Indications for Use (Describe)
MERICRON XL suture is intended for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery and ophthalmic 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)

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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: Feb 26, 2016

II. Device

Sr. No.	Trade / Proprietary Name	Common Name	Classification	Regulatory Class	Product Code	Regulation Number	Review Panel
1.	**FILASILK™** Natural Non-absorbable Silk Surgical Suture	Natural Non-absorbable Silk Surgical Suture	Suture, Non absorbable, Silk	II	GAP	878.5030	General & Plastic Surgery
2.	**FILAMIDE™** Non Absorbable Polyamide Surgical Sutures	Non-absorbable Polyamide Surgical Suture	Suture, Non absorbable, Synthetic, Polyamide	II	GAR	878.5020	General & Plastic Surgery
3.	**MERICRON XL™** Non Absorbable Polyester Surgical Suture	Non absorbable Poly (Ethylene Terephthalate) Suture	Suture, Non absorbable, Synthetic, Poly (Ethylene Terephthalate)	II	GAT	878.5000	General & Plastic Surgery
4.	**FILAPROP™** Non Absorbable Polypropylene Surgical Suture	Non-absorbable Polypropylene Surgical Suture	Suture, Non absorbable, Synthetic, Polypropylene	II	GAW	878.5010	General & Plastic Surgery

III. Predicate Device

Sr. No.	Meril's Suture Trade / Proprietary Name	Predicate Device Name	Predicate Device 510(k) No.
1.	**FILASILK™** Natural Non-absorbable Silk Surgical Suture	TRUSILK	K041514
2.	**FILAMIDE™** Non Absorbable Polyamide Surgical Sutures	TRULON	K041510
3.	**MERICRON XL™** Non Absorbable Polyester Surgical Suture	TRUBOND	K041512
4.	**FILAPROP™** Non Absorbable Polypropylene Surgical Suture	PROLENE	K133356

IV. Device Description

a. FILASILK™ Natural Non-absorbable Silk Surgical Suture

FILASILK™ silk suture is a non-absorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori* (*B. mori*) of the family Bombycidae. **FILASILK™** sutures are processed to remove the natural waxes and gums.

FILASILK™ suture is available undyed or dyed black with Logwood extract and coated with bees wax. FILASILK™ suture meets requirements established by the United States Pharmacopoeia (U.S.P.) for non-absorbable surgical suture.

b. FILAMIDE™ Non Absorbable Polyamide Surgical Sutures

FILAMIDE™ suture is a non-absorbable, sterile, synthetic, monofilament surgical suture composed of polyamide 6 $[(NH\text{-}CO\text{-}(CH_2)_5]_n$ and Polyamide 6,6 $(NH(CH_2)_6\text{-}NH\text{-}CO\text{-}(CH_2)_4\text{-}CO)_n$. FILAMIDE™ sutures are dyed with Logwood extract. Available in a broad range of suture sizes and lengths, FILAMIDE™ is either non-needled or attached to standard stainless steel needles of varying types and sizes.

c. MERICRON XL™ Non Absorbable Polyester Surgical Suture

MERICRON XL™ suture is a coated, braided, non-absorbable sterile surgical suture composed of poly (ethylene terephthalate). The empirical molecular formula of the polymer is $(C_{10}H_8O_4)_n$. The suture is coated with bees wax which acts as a lubricant to mechanically improve the ease of passage through tissue and the overall handling quality of the suture.

MERICRON XL™ is available undyed or dyed green with D & C Green No.6. **MERICRON XL™** is available in a range of gauge sizes and lengths, or attached to standard stainless steel needles of various types and sizes

d. FILAPROP™ Non Absorbable Polypropylene Surgical Suture

FILAPROP™ suture is a monofilament, synthetic non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula of polypropylene is $(C_3H_6)_n$. **FILAPROP™** sutures are dyed with phthalocyanine blue.

FILAPROP™ is available in a range of gauge sizes and lengths attached to standard stainless steel needles of various types and sizes

V. Intended Use

a. FILASILK™ Natural Non-absorbable Silk Surgical Suture

FILASILK™ is intended for use as non-absorbable sutures in general soft tissue approximation and/or ligation including use in cardiac, vascular and ophthalmic procedures.

b. FILAMIDE™ Non Absorbable Polyamide Surgical Sutures

FILAMIDE™ Non-absorbable Polyamide Surgical suture is indicated for use in soft tissue approximation and/ or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

c. MERICRON XL™ Non Absorbable Polyester Surgical Suture

MERICRON XL™ suture is intended for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurological and ophthalmic procedures.

d. FILAPROP™ Non Absorbable Polypropylene Surgical Suture

FILAPROP™ sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

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 – Dye / Un-dyed
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. Suture Length
11. Labeling 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. Suture Length
5. 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 Surgical Sutures are composed of the same materials, as are the predicate devices and has the same design, as do the predicate.

The subject devices are offered with the same colorants as predicate devices i.e. Logwood extract black used in **FILASILK™ & FILAMIDE™** is in accordance to 21 CFR 73.1410**,** D&C Green No. 6 used in **MERICRON XL™** is in accordance with 21 CFR 74.3206 & Phthalocyanine blue used in **FILAPROP™** is in accordance with 21 CFR 74. 3045).

Performance testing of the Meril sutures complies the USP requirements i.e. suture diameter, suture length, knot pull tensile strength, extractable color, suture-needle

attachment and sterility. However, **FILAMIDE™** & **FILAPROP™** may be slightly oversize in diameter to U.S.P. requirement for some suture sizes.