DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 11, 2017

Ethicon, Inc.
Ms. Debbie Fazen
Senior Regulatory Affairs Program Lead
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K163152
Trade/Device Name: Prolene Soft Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: February 10, 2017
Received: February 13, 2017

Dear Ms. Fazen:

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,

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)*
K163152

Device Name
Prolene Soft Polypropylene Mesh

Indications for Use *(Describe)*
Prolene Soft Polypropylene Mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92

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510(k) Number: K163152
Date Prepared: March 10, 2017
Device Trade Name: PROLENE® Soft Polypropylene Mesh
Device Common Name: PROLENE Soft Mesh
Class: Class II
Classification: 21 CFR 878.3300 – Surgical Mesh
Product Code: FTL
Predicate Device:

Device	Company	Product Code	510(k) Number	Predicate for
PROLENE® Soft Polypropylene Mesh	Ethicon, Inc.	FTL	K001122	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

Device Description

PROLENE Soft Mesh is a sterile, nonabsorbable synthetic surgical mesh designed for the repair of hernias and other fascial defects. The implant device is composed of knitted filaments of extruded polypropylene. Blue PROLENE™ monofilaments have been integrated to produce contrast striping in the mesh.

PROLENE Soft Mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of 3.5 mil diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE Mesh. Polypropylene material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

PROLENE Soft Mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property is designed to allow adaption to various stresses encountered in the body.

Indications for Use

The PROLENE Soft Polypropylene Mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The Indications for Use on the Prolene Soft Mesh 50 cm x 50 cm subject device is identical to the predicate device.

Summary of Technological Characteristics

The predicate and subject devices function in the same manner. They are designed as prosthetic material for the repair of hernias and other fascial deficiencies by providing reinforcement or acting as bridging materials. The technological characteristics of the subject device are different as compared to the predicate device. Both predicate and subject PROLENE Soft Mesh devices are composed of a macro porous non-absorbable synthetic surgical mesh. The additional size (50 cm x 50 cm) of the subject device has been developed to satisfy customer needs.

The safety and effectiveness and substantial equivalence of the predicate device and subject device has been demonstrated via data collected during design validation and design verification. The results of these tests provide reasonable assurance that the subject device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. All materials used in the proposed device are the same as the predicate device and meet the requirements of ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process.

Performance Data

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

1. Biocompatibility - PROLENE Soft Mesh is a permanent (>30 days) implant device contacting tissue. The biocompatibility for PROLENE Soft Mesh 50 cm x 50 cm has been evaluated in accordance with ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Evaluation and Testing", and ANSI/AAMI ST72:2011 "Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing." Endotoxin testing was performed in accordance with ANSI/AAMI ST72:2011 and met criteria of < 20 EU average/device.
2. Sterility - EO/ECH residual testing in accordance with ISO 10993-7:2008 was completed to verify that acceptable EO and ECH limits can be achieved for the subject device after exposure to the validated sterilization cycles. In conclusion, the subject device has a relatively low affinity for EO/ECH sterilization residues. Natural Product Resistance Testing (NPRT) and Comparative Resistance Testing was performed and results confirmed the subject device had met acceptance criteria. Bioburden testing, in accordance with ISO 11737-1, confirmed that the subject device had met the defined acceptance criteria. Overall, the sterility validation demonstrated that subject PROLENE Soft Mesh (50 cm x 50 cm) achieves a sterility assurance level of 10^{-6}.
3. Bench Testing – Bench top testing was performed to assess the physical/performance characteristics of the new device. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (March 2, 1999), the bench top testing evaluated physical characteristics of mesh including mesh knitting pattern, mesh pore size/porosity, mesh density, mesh thickness, and mesh stiffness as well as mesh performance testing including mesh burst strength and suture pullout strength.

Summary of Substantial Equivalence Comparison

The subject device, PROLENE Soft Mesh 50 cm x 50 cm, is equivalent to the predicate PROLENE Soft Mesh described in 510(k) K001122 with the exception of the size of the mesh patch. In accordance with Appendix A, 510(k) Decision Making flow chart from FDA's guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", the predicate device is legally marketed, the labeling is consistent with the IFU statements, the devices (predicate and subject) have the same intended use. The larger size is a new technological characteristic, however, it does not raise questions of safety and effectiveness.

The subject device and the predicate device share:

- the same operating principle,
- the same intended use,
- the same materials,
- the same packaging materials,
- the same labeling components,
- the same sterilization process (Ethylene Oxide),

- the same sterility assurance level (SAL) is 10^{-6} and
- the same shelf life

In summary, the proposed device, PROLENE Soft Mesh 50 cm x 50 cm, is substantially equivalent to the predicate device.

Conclusions

Clinical literature evidence and performance data support that the device is as safe and as effective as the predicate device for the intended use. Thus we conclude that the proposed device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act