DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 5, 2017

Ethicon Incorporated
Ms. Stephanie Saati
Senior Regulatory Affairs Specialist
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K172089
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: July 10, 2017
Received: July 11, 2017

Dear Ms. Saati:

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)*
K172089

Device Name
PROLENE™ Soft Polypropylene Mesh

Indications for Use *(Describe)*
PROLENE™ Soft Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing 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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ETHICON
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon, Inc. a Johnson & Johnson company
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Contact Person: Stephanie Saati
Senior Regulatory Affairs Specialist
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Date Prepared: June 30, 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 Product Code: SPM3XL	Ethicon, Inc.	FTL	K163152	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics
PROLENE™ Soft (Polypropylene), Nonabsorbabale Synthetic Surgical Mesh Product Codes: SPMH SPMII SPMLI SPMS SPMXS SPMXXL	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 abdominal wall hernias and abdominal wall deficiencies. 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 reduced 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.

Indications for Use:

PROLENE™ Soft Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.

Summary of Technological Characteristics:

PROLENE™ Soft Polypropylene Mesh is identical to the PROLENE™ Soft Polypropylene Mesh (K163152) and PROLENE™ Soft (Polypropylene), Nonabsorbabale Synthetic Surgical Mesh (K001122) marketed mesh with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the labeling (Instructions for Use) which has been revised to add a new Contraindication. Additionally, several other sections of the Instructions for Use of the subject device have been reworded/ reformatted for clarity to address evolving regulatory expectations and bring the contents of the Instructions for Use up to date.

Substantial Equivalence:

PROLENE™ Soft Polypropylene Mesh is identical to the PROLENE™ Soft Polypropylene Mesh (K163152) and PROLENE™ Soft (Polypropylene), Nonabsorbabale Synthetic Surgical Mesh (K001122) marketed mesh with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the labeling (Instructions for Use) which has been revised to add a new Contraindication. Additionally, several other sections of the Instructions for Use of the subject device have been reworded/ reformatted for clarity to address evolving regulatory expectations and bring the contents of the Instructions for Use up to date. The Indication statement of the subject mesh has been modified to add clarity. The Indication of the subject device does not introduce any new indications or expand patient population of the predicate mesh.

Conclusion:

The subject mesh, PROLENE™ Soft Polypropylene Mesh is identical to the two predicate marketed meshes, PROLENE™ Soft Polypropylene Mesh (K163152) and PROLENE™ Soft (Polypropylene), Nonabsorbabale Synthetic Surgical Mesh (K001122) with respect to intended use, technological characteristics, material, construction, specification, manufacturing and sterilization. In conclusion, the subject PROLENE™ Soft Polypropylene Mesh is substantially equivalent to the two predicate meshes.