Ethicon Inc
℅ Ms. Melina Escobar
Regulatory Affairs Specialist
P.O. Box 151
U.S. Route 22 West
Somerville, New Jersey 08876

July 2, 2018

Re: K180910
Trade/Device Name: ULTRAPRO™ Mesh and ULTRAPRO ADVANCED™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 5, 2018
Received: April 6, 2018

Dear Ms. Escobar:

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 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,

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)*
K180910

Device Name
ULTRAPRO™ Mesh
ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh

Indications for Use *(Describe)*
ULTRAPRO™ 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.

ULTRAPRO ADVANCED™ 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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510(k) Summary

Submitter:	Ethicon, Inc. a Johnson & Johnson company P.O. Box 151 Route 22 West Somerville, NJ 08876-0151
Contact Person:	Melina Escobar Regulatory Affairs Specialist Phone: 908-218-2583 Fax: 908-218-2595 Email: mescob14@its.jnj.com
Date Prepared:	April 5, 2018
Device Trade Name:	ULTRAPRO™ Mesh ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh
Device Common Name:	ULTRAPRO™ Mesh ULTRAPRO ADVANCED™
Class:	Class II
Classification:	21 CFR 878.3300 – Surgical Mesh
Product Code:	FTL

Predicate Device:

Device	Company	Product Code	510(k) Number	Predicate for
ULTRAPRO™ Mesh	Ethicon, Inc.	FTL	K033337	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics
ULTRAPRO ADVANCED	Ethicon, Inc.	FTL	K150906	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

Device Description:

ULTRAPRO™ Mesh is manufactured from approximately equal parts* of absorbable poliglecaprone-25 monofilament fiber and nonabsorbable polypropylene monofilament fiber. The polymer of the undyed and dyed polypropylene fiber (phthalocyanine blue, Color Index No.: 74160) is identical to the material used for dyed/undyed PROLENE™ suture material. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL™ suture. After absorption of the poliglecaprone-25 component, only the polypropylene mesh remains. The structure and size of this remaining mesh are optimally designed for the physiological stresses of the abdominal wall.

ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh is a sterile, partially absorbable mesh*, designed for the repair of abdominal wall hernias and other abdominal wall deficiencies. The device is manufactured out of dyed (phtalocyanine blue) and undyed non-absorbable polypropylene monofilaments (3.5 mil PROLENE™) as well as a twist, composed of dyed (phtalocyanine blue) and undyed non-absorbable polypropylene monofilaments (3.5 mil PROLENE™) and undyed absorbable poliglecaprone 25 monofilaments (5 mil MONOCRYL™). Blue stripes provide orientation.

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Indications for Use:

ULTRAPRO™ 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.

ULTRAPRO ADVANCED™ 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:

ULTRAPRO Mesh is identical to the ULTRAPRO Mesh (K033337) marketed mesh with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device. The device differs only in the labeling which certain 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.

ULTRAPRO ADVANCED is identical to the ULTRAPRO ADVANCED (K150906) marketed mesh with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device. The device differs only in the labeling which has been revised to reworded/ reformatted most of the Instructions for Use sections for clarity to address evolving regulatory expectations and bring the contents of the Instructions for Use up to date.

Substantial Equivalence:

ULTRAPRO™ Mesh and ULTRAPRO ADVANCED are identical to the ULTRAPRO™ Mesh (K033337) and ULTRAPRO ADVANCED (K150906) 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). Where several sections of the Instructions for Use of the subject devices have been reworded/ reformatted for clarity to address evolving regulatory expectations and bring the contents of the Instructions for Use up to date and aligned within the Mesh Harmonization project noted in the Cover Letter. The Indication statement of the subject meshes have been modified to add clarity. The Indication of the subject devices do not introduce any new indications or expand the patient population of the predicate meshes.

Conclusion:

The subject mesh, ULTRAPRO™ Mesh and ULTRAPRO ADVANCED are identical to the predicate marketed meshes, ULTRAPRO™ Mesh (K033337) and ULTRAPRO ADVANCED (K150906) with respect to intended use, technological characteristics, material, construction, specification, manufacturing and sterilization. In conclusion, the subject ULTRAPRO™ Mesh and ULTRAPRO ADVANCED are substantially equivalent to the predicate meshes.