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

Ethicon Incorporated
Ms. Susan Lin
Manager Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

July 24, 2015

Re: K150906
Trade/Device Name: ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: June 26, 2015
Received: June 26, 2015

Dear Ms. Lin:

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" (21CFR 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,

Joshua C. Nipper -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)*
K150906

Device Name
ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh

Indications for Use *(Describe)*
ULTRAPRO ADVANCED™ Mesh may be used for the repair of abdominal fascial deficiencies, such as hernias, 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

Applicant: Ethicon Inc.
P.O. Box 151
Route 22 West
Somerville, NJ 08876
USA
Phone: +1-908-218-2256
Fax: +1-908-218-2595

Date: March 31st, 2015

Contact Person: Thomas Greiner

Proprietary Device Name: ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh

Common Device Name: Surgical Mesh

Classification: Class II
21 CFR 878.3300 – Surgical Mesh, polymeric;
Product Code: FTL

Predicate Device: ETHICON Ultrapro™ Mesh - (K033337)

Manufacturer: Johnson & Johnson MEDICAL GmbH
Robert-Koch-Strasse 1
22851 Norderstedt
Germany

Description of the Device Subject to Premarket Notification:

ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh is a sterile, partially absorbable mesh device designed for the repair of hernias and other fascial defects. The implant device is composed of a macroporous mesh, manufactured out of dyed (phtalocyanine blue) and undyed non absorbable polypropylene monofilaments (3.5 mil PROLENE™) as well as a twist yarn, composed of dyed (phtalocyanine blue) and undyed non absorbable polypropylene monofilaments (3.5 mil PROLENE™) and undyed absorbable poliglecaprone 25 monofilaments (5 mil MONOCRYL™). The mesh provides blue stripes for orientation.

Indications for Use:

ULTRAPRO ADVANCED™ Mesh may be used for the repair of abdominal fascial deficiencies, such as hernias, that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Summary of Characteristics of New Device to Predicate Devices:

The principle of operation and fundamental scientific technology of the new device are equivalent to the predicate device. The ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh and its predicate device 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 new device are similar to the predicate device. Similar to ETHICON Ultrapro Mesh™, the new device is composed of a macroporous partially absorbable mesh.

Performance Data:

ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh underwent an extensive safety and performance testing program, including bench and animal testing, to demonstrate that the device meets the requirements as defined in user specifications, performs as intended, and is substantially equivalent to the predicate device. The tests conducted include:

- Biocompatibility testing in accordance to the tests recommended in the ISO 10993-1 standard was conducted. The results indicate that the device is biocompatible per this standard.
- 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.
- Pre-clinical efficacy studies were performed including a 28 day pilot study of ULTRAPRO ADVANCED™ Mesh designed to evaluate tissue integration, tissue reaction and mesh compression and a 28 and 91 day definitive study of ULTRAPRO ADVANCED™ Mesh designed to evaluate tissue integration and tissue reaction.

Conclusion

The ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh has the same intended use and fundamental scientific technology as its predicate device. Performance data demonstrates 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.