July 26, 2018

Ethicon, Inc.
Ms. Melina Escobar
Regulatory Affairs Specialist
Route 22 West
P.O Box 151
Somerville, New Jersey 08876-0151

Re: K181268
Trade/Device Name: PROLENE (Polypropylene) 3D Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 10, 2018
Received: May 14, 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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181268

Device Name
PROLENE (Polypropylene) 3D Patch

Indications for Use *(Describe)*
The PROLENE™ 3D Patch is indicated for the repair of groin hernia defects that require 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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ETHICON
a Johnson & Johnson company

**510(k) Summary**

| | |
|---|---|
| **Submitter:** | Ethicon, Inc. a Johnson & Johnson company<br>P.O. Box 151<br>Route 22 West<br>Somerville, NJ 08876-0151 |
| **Contact Person:** | Melina Escobar<br>Regulatory Affairs Specialist<br>Phone: 908-218-2583<br>Fax: 908-218-2595<br>Email: mescob14@its.jnj.com |
| **Date Prepared:** | May 10, 2018 |
| **Device Trade Name:** | PROLENE™ (Polypropylene) 3D Patch, Nonabsorbable Synthetic Surgical Mesh |
| **Device Common Name:** | PROLENE™ 3D Patch |
| **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™ (Polypropylene) 3D Patch | Ethicon, Inc. | FTL | K010722 | Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics |

**Device Description:**

PROLENE™ 3D Patch is a device comprised of nonabsorbable (polypropylene) components. The polymer of the polypropylene filaments is identical to the material used in PROLENE™ Suture. It consists of a flat mesh onlay patch secured to a formed expandable diamond-shaped mesh patch component. The expandable patch portion of the device is a hollow diamond-shaped component that is deployed through the use of an integrated, looped, polyester thread.

**Indications for Use:**

The PROLENE™ 3D Patch is indicated for the repair of groin hernia defects that require a reinforcing material to obtain the desired surgical result.

**Summary of Technological Characteristics:**

PROLENE™ (Polypropylene) 3D Patch is identical to the PROLENE™ (Polypropylene) 3D Patch (K010722) marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device.

The device differs in the labeling (Instructions for Use) which has been reworded/ reformatted to address evolving regulatory expectations and bring the contents of the Instructions for Use up to date.

**Substantial Equivalence:**

PROLENE™ (Polypropylene) 3D Patch is identical to the PROLENE™ (Polypropylene) 3D Patch, Nonabsorbable Synthetic Surgical Mesh (K010722) marketed mesh with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The device differs 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™ (Polypropylene) 3D Patch is identical to the predicate marketed mesh, PROLENE™ (Polypropylene) 3D Patch, Nonabsorbable Synthetic Surgical Mesh (K010722) with respect to intended use, technological characteristics, material, construction, specification, manufacturing and sterilization. In conclusion, the subject devices are substantially equivalent to the predicate devices.