June 28, 2018

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

Re: K180829
Trade/Device Name: PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh,
PROLENE™ (Polypropylene) Hernia System, Non-absorbable Synthetic Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 29, 2018
Received: March 30, 2018

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.

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
Indications for Use

PROLENE™ Mesh Polypropylene Non-Absorbable Synthetic Surgical Mesh
PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh

Indications for Use (Describe)
PROLENE™ 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.

The PROLENE™ Hernia System is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect).

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
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Somerville, NJ 08876-0151

Contact Person: Stephanie Saati
Senior Regulatory Affairs Program Lead
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Email: SSaati@its.jnj.com

Date Prepared: March 28, 2018

Device Trade Name: PROLENE™ Polypropylene Mesh Non-Absorbable
Synthetic Surgical Mesh

PROLENE™ (Polypropylene) Hernia System,
Nonabsorbable Synthetic Surgical Mesh

Device Common Name: PROLENE™ Mesh

PROLENE™ Hernia System

Class: Class II

Classification: 21 CFR 878.3300 – Surgical Mesh

Product Code: FTL
Predicate Devices:

PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh

<table>
<thead>
<tr>
<th>Device</th>
<th>Company</th>
<th>Product Code</th>
<th>510(k) Number</th>
<th>Predicate for</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROLENE™ Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh</td>
<td>Ethicon, Inc.</td>
<td>FTL</td>
<td>K962530</td>
<td>Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics</td>
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</tbody>
</table>

PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh

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<thead>
<tr>
<th>Device</th>
<th>Company</th>
<th>Product Code</th>
<th>510(k) Number</th>
<th>Predicate for</th>
</tr>
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</table>

Device Description:

PROLENE™ Mesh is a sterile, nonabsorbable synthetic surgical mesh designed for the repair of abdominal wall hernias and abdominal wall deficiencies. The implant device 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, LLC). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

PROLENE™ 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 fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional, elastic property allows adaptation to various stresses encountered in the body.

PROLENE™ Hernia System is a sterile, pre-shaped, three-dimensional device designed for the repair of abdominal wall hernia defects, including inguinal (direct & indirect). It is constructed of an onlay patch connected by a mesh cylinder to a circular or oblong underlay patch. The material is undyed PROLENE™ (Polypropylene) Mesh constructed of knitted nonabsorbable polypropylene filaments.

**Indications for Use:**

PROLENE™ 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.

The PROLENE™ Hernia System is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect).

**Summary of Technological Characteristics:**

PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh is substantially equivalent to the PROLENE™ Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh (K962530) predicate device with respect to technological characteristics. Both the subject and predicate devices are constructed of knitted filaments of extruded polypropylene. The devices function in the same manner and are designed to provide reinforcement to repair abdominal wall hernias and abdominal wall deficiencies. The subject mesh is manufactured within the existing manufacturing processes for the predicate device. There are no changes to the manufacturing, packaging, sterilization processes, or shelf life of the currently marketed device.

PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh is substantially equivalent to the PROLENE™ (Polypropylene) Hernia System.
System, Nonabsorbable Synthetic Surgical Mesh (K984220) predicate device with respect to technological characteristics. Both the subject and predicate devices are sterile, pre-shaped, three-dimensional devices constructed of an onlay patch connected by a mesh cylinder to a circular or oblong underlay patch. The material used in both devices is undyed PROLENE™ (Polypropylene) mesh constructed of knitted nonabsorbable polypropylene filaments. Both the subject and predicate devices function in the same manner and are designed for the repair of abdominal wall hernia defects, including inguinal (direct & indirect). There are no changes to the manufacturing, packaging, and sterilization processes, or shelf life of the currently marketed device.

The subject PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh and PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh, for which this 510(k) Premarket Notification- Change being Effected is being submitted, differs from the currently marketed devices, K962530 and K984220, in the labeling (Instructions for Use). The Instructions for Use has been revised to add a new Contraindication. Additionally, several other 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.

**Substantial Equivalence:**

PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh is substantially equivalent to the PROLENE™ Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh (K962530) predicate device. Both the subject and predicate devices are constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE™ Polypropylene Suture, nonabsorbable surgical sutures. The principle of operation of the subject PROLENE™ Mesh, which is to provide reinforcement to repair abdominal wall hernias and abdominal wall deficiencies, is equivalent to that of the predicate device. The subject device is manufactured within the existing manufacturing processes for the predicate device. There are no changes to the packaging, sterilization processes, or shelf life of the currently marketed device.

PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh is substantially equivalent to the PROLENE™ (Polypropylene) Hernia
System, Nonabsorbable Synthetic Surgical Mesh (K984220) predicate device. Both the subject and predicate devices are sterile, pre-shaped, three-dimensional devices constructed of an onlay patch connected by a mesh cylinder to a circular or oblong underlay patch. The material is undyed PROLENE™ (Polypropylene) mesh constructed of knitted nonabsorbable polypropylene filaments. The principle of operation of the subject PROLENE™ (Polypropylene) Hernia System, which is to provide reinforcement to repair abdominal wall hernia defects, including inguinal (direct & indirect) hernias, is equivalent to that of the predicate device. There are no changes to the manufacturing, packaging, and sterilization processes, or shelf life of the currently marketed device.

The subject PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh and PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh differ from their respective predicate devices, K962530 and K984220, in the labeling (Instructions for Use). The Instructions for Use has been revised to add a new Contraindication. Additionally, several other 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. The Indication statement of the subject devices has been modified to add clarity and does not introduce any new indications or expand patient population of the predicate device.

**Conclusion:**

Based on the intended use, fundamental scientific technology and, technological characteristics, the subject devices PROLENE™ Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh and PROLENE™ (Polypropylene) Hernia System, Nonabsorbable Synthetic Surgical Mesh are considered to be substantially equivalent to their predicate devices, K962530 and K984220 respectively.