DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 23, 2014

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

Re: K141560
Trade/Device Name: ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 17, 2014
Received: September 19, 2014

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,

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

4 INDICATIONS FOR USE STATEMENT

510(k) No (if known): _____

Device Name: ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device

Indications for Use: ETHICON PHYSIOMESH™ Open may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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:	October 23, 2014
Contact Person:	Susan Lin
Proprietary Device Name:	ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device
Common Device Name:	Surgical Mesh
Classification:	Class II 21 CFR 878.3300 – Surgical Mesh, polymeric; Product Code: FTL
Predicate Devices:	ETHICON PHYSIOMESH™ Flexible Composite Mesh - (K093932) BARD Ventrio™ ST Hernia Patch - (K101920) Parietex™ Optimized Composite Mesh (PCO) - (K110816)
Manufacturer:	Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 22851 Norderstedt Germany

5.1 Description of the Device Subject to Premarket Notification:

ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device is a sterile, partially absorbable skirted mesh device designed for the repair of hernias and other fascial defects. The implant device is composed of a macroporous mesh, knitted from polypropylene and polydioxanone fibers, laminated to an absorbable poliglecaprone 25 film that is intended to physically separate the mesh from underlying tissue and organ surfaces thereby reducing unintended tissue attachment to the mesh. The perimeter edges are prefolded to create the fixation skirt that facilitates manual placement and positioning against the intra-abdominal wall, while allowing for the use of mechanical fixation devices.

5.2 Indications for Use:

ETHICON PHYSIOMESH™ Open may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

5.3 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 devices. The ETHICON PHYSIOMESH™ Open Device and the predicate devices 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 devices. Similar to ETHICON PHYSIOMESH™, the new device is composed of a macroporous mesh coated with an absorbable tissue separation film. Similar to BARD Ventrio™ ST Hernia Patch and Parietex™ Optimized Composite Mesh (PCO), ETHICON PHYSIOMESH™ Open Device has a fixation skirt that facilitates manual placement and positioning against the intra-abdominal wall, while allowing for the use of mechanical fixation devices.

5.4 Performance Data:

ETHICON PHYSIOMESH™ Open Device 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 devices. 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 14-day rabbit sidewall model study designed to evaluate potential for adhesion formation and a 91-day swine two-stage incisional hernia model study designed to evaluate tissue integration and reaction as well as mesh compression.

5.5 Conclusion

The ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device has the same intended use and fundamental scientific technology as its predicate devices. Performance data demonstrates that the device is as safe and as effective as the predicate devices for the intended use. Thus we conclude that the proposed device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.