K093932
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510(K) SUMMARY

APR - 9 2010

1. Submitter Name:

ETHICON, INC.
P.O. Box 151
Route 22 West
Somerville, J.J. 08876
Phone: + 1.908.218.3323
FAX: + 1.908.218.2595

2. Date:

March 18, 2010

3. Contact Information:

Neelu Medhekar
Director, Regulatory Affairs
ETHICON, INC.
Phone: + 1.908.218.3323
FAX: +1.908.218.2595

4. Substantially Equivalent To:

The ETHICON PHYSIOMESH™ is substantially equivalent to:

PROCEED Mesh (K031925 & K060713)	For Indications for Use and technological characteristics
ULTRAPRO Hernia System (K071249)	For technological characteristics related to the poligelcaprone 25 Film
ULTRAPRO Mesh (K033337)	For technological characteristics related to the mesh materials poliglecaprone 25 & polypropylene

5. Description of the Device Subject:

ETHICON PHYSIOMESH™, Flexible Composite Mesh, is a sterile, low profile, flexible composite mesh designed for the repair of hernias and other fascial deficiencies. The mesh product is composed of a nonabsorbable, macroporous polypropylene mesh laminated between two undyed polyglecaprone-25 films. An undyed polydioxanone film provides the bond between the polyglecaprone-25 film and polypropylene mesh. The polypropylene component is constructed of knitted filaments of extruded polypropylene. An additional dyed polydioxanone film marker has been added for orientation purposes.

6. Indications for Use:

ETHICON PHYSIOMESH™ 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.

7. Performance Data:

ETHICON PHYSIOMESH™, Flexible Composite Mesh underwent a comprehensive bench, and animal testing program and passed all intended criteria in accordance with appropriate test protocols and standards. During bench testing the device was subject to testing such as device thickness, pore size, burst strength, device weight, tensile strength, device stiffness, suture pullout strength, burst strength and tear resistance. Additionally, in-vitro and in-vivo testing was provided showing that the device performed as intended.

8. Overall Performance Conclusion:

ETHICON PHYSIOMESH™, Flexible Composite Mesh met all testing criteria, demonstrated substantial equivalence to its predicate devices and did not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 9 2010

Ethicon, Inc.
% Neelu Medhekar
Director, Regulatory Affairs
P.O. Box 151, Route 22 West
Somerville, New Jersey 08876

Re: K093932
Trade/Device Name: Ethicon Physiomesh™, Flexible Composite Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 19, 2010
Received: March 22, 2010

Dear Neelu Medhekar:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE

510(k) No (if known): _____

Device Name: ETHICON PHYSIOMESH™, Flexible Composite Mesh

Indications for Use:

ETHICON PHYSIOMESH™ 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.

Prescription Use _____√_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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