MAY 30 2014

510(K) SUMMARY

Applicant: Ethicon Inc.
P.O. Box 151
Route 22 West
Somerville, NJ 08876
USA
Phone: +1-908-218-3323
Fax: +1-908-218-2595

Date: May 12, 2014

Contact Person: Rey Librojo

Proprietary Device Name: ULTRAPRO COMFORT PLUG™
Partially Absorbable Hernia Repair Device

Common Device Name: Surgical Mesh

Classification: Class II
Regulation Number 878.3300 – Surgical Mesh, polymeric;
Product Code: FTL

Predicate Devices: ULTRAPRO PLUG™ (ETHICON, Inc.) - K070224;
BARD Mesh Perfix™ Plug (Davol, Inc.) - K922916

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

Description of the Device Subject to Premarket Notification:

ULTRAPRO COMFORT PLUG™ is a sterile, single-use partially absorbable hernia repair device designed for open extra-peritoneal abdominal wall repair, particularly groin hernia repair, to provide permanent support during and following wound healing. ULTRAPRO COMFORT PLUG™ consists of a three-dimensional plug, which fills the defect and a flat pre-shaped onlay patch, which lays on the defect to reinforce the weak area around the defect. The Plug is composed of an undyed ULTRAPRO™ Mesh. Dyed ribs, made from dyed (D&C Violet No. 2) polydioxanone polymer film, are laminated to the Plug mesh. The onlay patch is a pre-shaped, dyed ULTRAPRO™ Mesh. The ULTRAPRO™ Mesh is manufactured from approximately equal parts of absorbable poliglecaprone 25 monofilament fibers and non-absorbable polypropylene monofilament fibers. The device is available in different sizes.

Indications for Use:

The ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

Summary of Technological Characteristics of New Device to Predicate Devices:

Similarity:
The principle of operation and fundamental scientific technology of the proposed device are equivalent to the predicate devices. ULTRAPRO COMFORT PLUG™ and the predicate devices function in the same manner – they are designed as plug plus onlay patch devices for open extra-peritoneal abdominal wall repair, particularly groin hernia repair. The polymer materials in the proposed device is identical to that of Ultrapro Plug, which is composed with approximately equal parts of absorbable poliglecaprone 25 monofilament fibers and non-absorbable, polypropylene monofilament fibers. The mash knitting structure of both plug and onlay patch of ULTRAPRO COMFORT PLUG™ is the same as the onlay patch material of ULTRAPRO Plug the proposed device has similar 3-D physical shapes as that of Bard Mesh Perfix Plug.
Difference:
The plug material for proposed device is composed of undyed ULTRAPRO™ Mesh. Dyed ribs, made from dyed (D&C Violet No. 2) polydioxanone polymer film, are laminated to the Plug mesh to provide better visibility to the plug for ease of insertion into the defect and fixation.

Performance Data:

ULTRAPRO COMFORT PLUG™, Partially Absorbable Hernia Repair Device underwent an extensive safety and performance testing program, including bench and animal testing, to support 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 10993-1:2009 standard including cytotoxicity, sentitization, irritation, acute systemic toxicity, pyrogenicity, subchronic toxicity, *genotoxicity,* and local tissue response and absorption study
- Bench testing including device dimensional measurement and comparison, and shelf life testing
- Performance testing in animal model including efficacy study evaluating mesh compression, tissue integration, and tissue reaction and infection potentiation study.

The ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device has the same intended use, fundamental scientific technology, and principles of operation 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.

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

May 30, 2014

Ethicon, Inc.
Reynaldo Librojo
Director, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, NJ 08876

Re: K133198
Trade/Device Name: ULTRAPRO COMFORT PLUG Partially Absorbable Hernia Repair Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 22, 2014
Received: May 28, 2014

Dear Mr. Reynaldo Librojo,

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): K133198

Device Name: ULTRAPRO COMFORT PLUG™
Partially Absorbable Hernia Repair Device

Indications for Use: The ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

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

Page 1 of 1

Peter L. Hudson -S