K042603

DEC 22 2004

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510(k) Summary

Trade Name: GYNECARE PROLENE Fastener System

Sponsor: ETHICON, inc.
Route 22 West
Somerville, NJ 08876

Contact: Sean O'Bryan, Senior Project Manager, Regulatory Affairs; Tel: 908-218-2456

Device Generic Name: Implantable staple, nonabsorbable (21 CFR 878.4750)

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: PBQ

Predicate Device(s): ETHIBOND EXCEL suture - NDA 17-804
ETHICON PROLENE suture - NDA 16-374

Product Description: The GYNECARE PROLENE Fastener consists of the implantable nonabsorbable PROLENE polypropylene Fastener.

Indications for Use:

The GYNECARE PROLENE Fastener System is indicated for the attachment of knitted, non-woven surgical mesh and suture to ligaments of the pelvic floor.

Safety and Performance:
The following safety and performance data has been provided to support substantial equivalence of the GYNECARE PROLENE Fastener System:

Performance testing:

- Design Verification of the GYNECARE PROLENE Fastener with a Distributed Load
- Design Verification of the GYNECARE PROLENE Fastener with a Point Load
- Design Verification for the Tensile Strength of the GYNECARE PROLENE Fastener with GYNECARE GYNEMESH* PS
- Design Verification for the In-Vivo Comparison Between the Tissue Pullout Force of Suture and the GYNECARE PROLENE Fastener
- Holding Strength of the GYNECARE PROLENE Fastener in the Sacrospinous Ligament

Conclusion:
Based on 1) safety and performance data, and 2) similarities in design, operating principles, biocompatibility and sterilization method, the GYNECARE PROLENE Fastener System has been shown to be substantially equivalent to 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

February 1, 2013

ETHICON, Inc.
% Mr. Sean O'Bryan
Senior Project Manager, Regulatory Affairs
Route 22 West
SOMERVILLE NJ 08876

Re: K042603
Trade/Device Name: Gynecare Prolene Fastener System
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: PBQ
Dated (Date on orig SE ltr): November 18, 2004
Received (Date on orig SE ltr): November 22, 2004

Dear Mr. O'Bryan:

This letter corrects our substantially equivalent letter of December 22, 2004.

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 (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.

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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042603

Indications for Use

510(k) Number (if known): K042603

Device Name: GYNECARE PROLENE Fastener System

Indications For Use:

The GYNECARE PROLENE Fastener System is indicated for the attachment of knitted, non-woven surgical mesh and suture to ligaments of the pelvic floor.

Prescription Use _X_____ 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042603