SL-2010-001

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Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

Submitted by:

Susan Lin
Manager, Regulatory Affairs
Ethicon, Inc., A *Johnson & Johnson* Company

Route 22 West, PO Box 151
Somerville, NJ 08876

JUL - 1 2010

Name/Classification of Device:

Class II in 21 CFR § 878.3300, Surgical Mesh / OTN

Trade Name:

GYNECARE TVT ABBREVO™ Continence System

Predicate Devices:

GYNECARE TVT™ Obturator System (K033568), ETHICON, Inc.

Statement of Intended Use:

The GYNECARE TVT ABBREVO™ Continence System is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description:

GYNECARE TVT ABBREVO™ device is a sterile, single-patient use device which consists of one piece of blue (phtalocyanine blue, color index number 74160) PROLENE™ polypropylene mesh (mesh implant) approximately 1.1 cm x 12 cm covered by a polyethylene sheath.

The Helical Passer Sheaths (white polyethylene tube receptacles) are attached along with the mesh implant sheath by PROLENE polypropylene Positioning Lines to each end of the mesh implant to accommodate the Helical Passers. The Helical Passers come assembled to the GYNECARE TVT ABBREVO™ device and are used to deliver the mesh implant via the trans-obturator 'inside-out" approach.. Further, there is a GYNECARE TVT ABBREVO™ Placement Loop consisting of a loop of PROLENE Polypropylene Monofilament with an attached polypropylene button, pre-assembled as part of the GYNECARE TVT ABBREVO™ Implant Assembly at the center of the mesh to aid in symmetric placement of the mesh.

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Summary of Technological Characteristics of New Device to Predicate Devices:

The principle of operation and fundamental scientific technology of the proposed device are equivalent to the predicate devices. Both the GYNECARE TVT™ Obturator and the GYNECARE TVT ABBREVO™ function in the same manner - Introducing a sub-urethral synthetic mesh sling in the patient from a vaginal incision that provides mid-urethral support.

Performance Data:

GYNECARE TVT ABBREVO™ underwent an extensive safety and performance testing program to support that GYNECARE TVT ABBREVO™ fulfills the device requirements defined in user specifications, functions as intended, and is substantially equivalent to the predicate device. The tests conducted include:

- Biocompatibility testing in accordance to the tests recommended in the ISO 10993-1 standard
- Bench top physical/performance measurements including Length of Positioning Line + Mesh and Attachment Strength
- Initial fixation force and anatomic pathway studies in cadaver model
- Tissue in-growth studies in animal model

Conclusions:

GYNECARE TVT ABBREVO™ has the same indications for use, principle of operation, and fundamental scientific technology as its predicate device. Performance data demonstrates that the device is as safe and effective as the predicate device 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Ethicon, Inc.
% Ms. Susan Lin
Manager, Regulatory Affairs
Route 22 West, P.O. Box 151
SOMERVILLE NJ 08876

SEP 28 2012

Re: K100936
Trade/Device Name: GYNECARE TVT ABBREVO™ Continence System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: April 2, 2010
Received: April 5, 2010

Dear Ms. Lin:

This letter corrects our substantially equivalent letter of July 7, 2010.

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" (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 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,

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

K100936

SL-2010-002

Indications for Use

510(k) Number (if known): _____

Device Name: GYNECARE TVT ABBREVO™ Continence System

Indications for Use:

The GYNECARE TVT ABBREVO™ Continence System is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X .
(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

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

510(k) Number K100936