K113205
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JUN 12 2012

Sponsor:

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Date of Submission: 13 January 2012

Proprietary Name: ARTISYN™ Y-Shaped Mesh

Common Name: Surgical Mesh

Regulation: 21 CFR878.3300

Regulatory Class: II

Product Codes: OTO – Mesh, Surgical, Gynecologic, For Apical Vaginal Prolapse, Transabdominally Placed.
FTL – Mesh, Surgical, Polymeric

Predicate Devices: ALYTE™ Y-Mesh Graft, CR BARD, K101722
GYNECARE GYNEMESH M® Partially Absorbable Mesh , ETHICON Inc., K082216
RESTORELLE® Y, Mpathy Medical Devices, Ltd., K092207

Device Description: ARTISYN™ Y-Shaped Mesh consists of two pieces of partially absorbable mesh provided in a Y shape: a vaginal section with anterior/posterior flaps and a sacral section. The anterior and posterior flaps are for anterior and posterior vaginal attachment, and the sacral flap for attachment to the sacral promontory. The mesh consists of non-absorbable undyed and dyed polypropylene and absorbable undyed poliglecaprone-25 monofilament. The

vaginal and sacral sections are sewn together using polypropylene monofilament. Blue polypropylene monofilaments have been incorporated in the mesh material to produce contrast striping. The vertical stripes on the sacral flap and the horizontal stripes on the anterior and posterior vaginal flaps help aid in positioning, trimming and suturing the mesh.

Indications for Use

ARTISYN™ Y-Shaped Mesh is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparatomy or laparascopic approach) where surgical treatment for vaginal vault prolapse is warranted.

Technological Characteristics Summary

ARTISYN™ Y-Shaped Mesh is composed of the same partially absorbable mesh material used in the predicate device, GYNECARE GYNEMESH M® Partially Absorbable Mesh. The design of the ARTISYN™ Y-Shaped Mesh is a Y configuration with a similar shape and similar dimensions as the predicate devices, BARD ALYTE™ Y-Mesh Graft and Mpathy MEDICAL RESTORELLE® Y.

Performance Data

Non-clinical performance of the ARTISYN™ Y-Shaped Mesh was characterized in accordance with FDA *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh,* March 22, 1999, to demonstrate substantial equivalence to the predicate devices. The mesh material used in the ARTISYN™ Y-Shaped Mesh device has been subjected to mechanical testing and is identical to the predicate, GYNECARE GYNEMESH M® Partially Absorbable Mesh, and substantially equivalent to the predicate, BARD ALYTE™ Y-Mesh Graft. The finished ARTISYN™ Y-Shaped Mesh device was subjected to mechanical testing and is substantially equivalent to the predicate devices, BARD ALYTE™ Y-Mesh Graft and Mpathy MEDICAL RESTORELLE® Y.

Conclusions

The data provided in this premarket notification demonstrate that the ARTISYN™ Y-Shaped Mesh is substantially equivalent to the predicate devices. All four devices have the same intended use, fundamental technology and principle of operation.

ARTISYN™ Y-Shaped Mesh and the three predicate devices, BARD ALYTE® Y-Mesh Graft, GYNECARE GYNEMESH M® Partially Absorbable Mesh and Mpathy MEDICAL RESTORELLE® Y are surgical mesh intended to support organs in the pelvic floor to address pelvic organ prolapse. ARTISYN™ Y-Shaped Mesh, BARD ALYTE® Y-Mesh Graft and Mpathy MEDICAL RESTORELLE® Y are the same shape and same approximate dimensions. ARTISYN™ Y-Shaped Mesh and GYNECARE GYNEMESH M® Partially Absorbable Mesh are made of the same mesh material.

Bench testing was performed in accordance with the FDA guidance document *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh,* March 22, 1999. Results show that all four devices provide similar performance.

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

JUN 11 2012

Ms. Sarah McManus
Manager, Regulatory Affairs
ETHICON Women's Health and Urology
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SOMERVILLE NJ 08876

Re: K113205
Trade/Device Name: ARTISYN™ Y-Shaped Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: May 18, 2012
Received: May 21, 2012

Dear Ms. McManus:

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,

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

Indications for Use Statement

510(k) Number (if known): K113205

Device Name: ARTISYN™ Y-Shaped Mesh

Indications for Use:

ARTISYN™ Y-Shaped Mesh is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparatomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use ___√___ and/or Over-the-Counter Use _____
21 CFR Part 801 Subpart D 21 CFR Part 801 Subpart C

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/11/2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113205