K112322

MAY 17 2012

510(k) Summary of Safety and Effectiveness Information

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Date Prepared: May 16, 2012

Device Name: Restorelle® Y

510(k) Number: K112322

Common Name: Surgical Mesh

Regulation: 21 CFR §878.3300

Regulatory Class: Class II

Product Code: OTO-Mesh, Surgical, Gynecological, For Apical Vaginal Prolapse, Transabdominally Placed.

Predicate Devices: ALYTE™ Y-Mesh Graft (Bard Medical K101722)
Restorelle Y Mesh (Mpathy Medical K092207)

Purpose of Submission: The purpose of this submission is to obtain a specific indication for use statement for sacrocolpopexy for the previously cleared Restorelle Y Mesh (K092207).

Description of Device: *Restorelle* Y is a mesh is constructed of knitted non-absorbable monofilaments of polypropylene, a synthetic polymer. It is designed for the treatment of vaginal vault prolapse. The Y shape design allows the two Y- leg segments to be attached to the anterior and posterior vaginal walls. The base of the Y segment is designed to attach to the sacral ligament.

Indications for Use: *Restorelle* Y is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Restorelle Y has same intended use as the ALYTE™ Y-Mesh Graft.

Technological Characteristics Summary: The Restorelle Y has different technological characteristics compared to the ALYTE™ Y-Mesh Graft (e.g. dimensions, pore size and density) which may affect safety and efficacy. However, these differences in technological characteristics do not raise new safety and effectiveness questions because the Restorelle Y is the same Restorelle Y Mesh cleared in K092207. Accepted scientific methods exist to assess these new characteristics as described in the following sections.

Non Clinical Testing: Non-clinical performance of the subject device 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 device intended for use of sacrocolposuspension. The following performance characteristics were evaluated:

- Mesh Thickness
- Pore Size
- Mesh Density
- Stiffness
- Tensile Strength
- Suture Pullout Strength
- Burst Strength

The results of non-clinical performance testing on Restorelle Y were acceptable.

Performance testing was performed on samples that were all subjected to shelf life validations and testing.

Biocompatibility Testing: Restorelle Y has been subjected to and successfully passed the following biocompatibility testing in accordance with ISO 10993:

- Cytotoxicity
- Irritation
- Sensitization
- Systemic toxicity
- Pyrogenicity
- Genotoxicity (Ames Bacterial Study)
- Implantation
- Hemolysis

Clinical Testing: An independent prospective cohort study was conducted to assess the subjective and objective outcomes using Restorelle Y and robotic sacrocolpoplexy for patients with prolapse stages 2-4 (see references below). The following results were reported after twelve month postoperative assessments:

- Objective anatomical cure rate was 89.1% (was defined as POP-Q Stage 0 or 1 at all postoperative intervals);

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- Clinical cure rate was 93.5% (was defined as by simultaneously considering POP-Q points and subjective measures);
- 78% of patients with preoperative dyspareunia reported resolution;
- 63% of patients were sexually active;
- 8% of patients developed new onset of dyspareunia;
- No mesh erosions occurred.

References:

Abstracts presented at AAGL 40th Global Congress of Minimally Invasive Gynecology (November 6-10, 2011 in Hollywood, FL)

- Bowel Function after Robotic Sacrocolpopexy: Christa Lewis DO, Charbel Salamon MD, Amir Shariati MD, Jennifer L. Priestley PhD, Emil Gurshumov MD, Patrick Culligan MD
- Prospective Cohort Study of Robotic Sacrocolpopexy using Lightweight Polypropylene Y Mesh; Charbel Salamon MD, Christa Lewis DO, Amir Shariati MD, Jennifer L. Priestley PhD, Emil Gurshumov MD, Patrick Culligan MD

Literature Reviews:

Restorelle Case Reports: Coloplast has conducted literature reviews that included case reports in which Restorelle mesh has been used in sacrocolpopexy. The case reports were as follows:

- North, C.E. et al. (2005) A preliminary study to compare the vaginal palpability of two different mesh materials used for laparoscopic sacrocolpopexy. *International Urogynecology Journal.*
- Hawthorn R. et al. (2007). Uses of an ultra light weight mesh in vaginal vault repairs to minimize complications A two-centre observation study. *British International Congress of Obstetrics and Gynaecology*
- North C. et al. (2007). The anatomical and function outcome laparoscopic sacrocolpopexy using an ultra light weight, polypropylene mesh. *International Urogynecology Journal*

Other Commercially Available Mesh Devices: Additional literature and clinical reviews were conducted for other mesh products. The criteria included the treatment of pelvic organ prolapse via open, robotic or laparoscopic sacrocolpopexy. The data from this review are supportive of the safety and effectiveness of synthetic mesh for sacrocolpopexy.

Conclusions: The performance data and clinical data on similar mesh devices provided in this submission demonstrate that the *Restorelle* Y mesh is substantially equivalent to its predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Silver Spring, MD 20993-0002

Coloplast A/S
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MAY 17 2012

Re: K112322
Trade/Device Name: Restorelle® Y
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: May 4, 2012
Received: May 7, 2012

Dear Mr. Crabtree:

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): __K112322__

Device Name: Restorelle® Y

Indications for Use: *Restorelle* Y is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112322