2. 510(k) Summary

AUG 2 2013

510(k) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
Phone/Fax:	Office: (612) 302-4922 Fax: (612) 287-4138
Name of Contact Person:	Tim Crabtree Regulatory Affairs Manager
Date Prepared:	July 2, 2013
Trade or Proprietary Name:	Restorelle M & XL Polypropylene Mesh
Common or Usual Name:	Surgical Mesh
Classification Name/	Mesh, Surgical, Gynecological, For Apical Vaginal Prolapse, Transabdominally Placed
CFR Number/Product Code:	21 CFR §878.3300/ OTO
Predicate Devices:	Restorelle L (K122440)

Description of Device: Restorelle M and Restorelle XL Polypropylene Mesh are provided as sterile mesh constructed of knitted non-absorbable monofilaments of polypropylene, a synthetic polymer. Restorelle M is a flat mesh measuring 10cm x 15cm. Restorelle XL is a flat mesh measuring 30cm x 30cm. Both are designed for the treatment of apical vaginal prolapse.

Indication for Use: Restorelle M and Restorelle XL Polypropylene Mesh devices are indicated for use as bridging material for sacrocolposuspension and/or sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Technological Characteristics Summary: The Coloplast Restorelle M and Restorelle XL Polypropylene Mesh devices share the same materials, features, intended use, and technological characteristics as Restorelle L. The following table lists the properties associated with the subject and predicate devices.

Property	Subject Devices Restorelle M & XL	Predicate Device Restorelle L
Indications	Restorelle M & XL Polypropylene Mesh devices are indicated for use as bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted	Restorelle L Polypropylene Mesh is indicated for use as bridging material for sacrocolposuspension/ sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted
Materials of Construction	Non-absorbable, monofilament polypropylene mesh	Non-absorbable, monofilament polypropylene mesh
Dimensions	10cm x 15cm (M) 30cm x 30cm (XL)	24cm x 8cm (L)
Shape	Flat	Flat
Pore Size (mm)	1.80 x 1.83	1.80 x 1.83
Sterilization Method	Ethylene Oxide	Same
Regulatory Status	Pending	Cleared K122440 (L)
Product Code	OTO	OTO

The only difference in between the subject and predicate devices is the mesh size. Therefore the proposed subject device is substantially equivalent to the referenced predicate devices for indications, materials and technological features.

Conclusions: The performance and non-clinical referenced demonstrate that the Restorelle M and XL Polypropylene Mesh devices are substantially equivalent to Restorelle L Polypropylene Mesh.

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

August 2, 2013

Coloplast A/S
% Tim Crabtree
Regulatory Affairs Manager
Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411

Re: K132061
Trade/Device Name: Restorelle M and Restorelle XL Polypropylene Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: July 2, 2013
Received: July 3, 2013

Dear Tim 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 contact 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. 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

1. **Statement of Indications for Use**

Indications for Use

510(k) Number (if known): K132061

Device Name: Restorelle M and Restorelle XL Polypropylene Mesh

Restorelle M and XL Polypropylene Mesh devices are indicated for use as bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K132061