JUN 24 2011

510(k) Summary

Submitter:	Coloplast A/S
Address	Holtedam 1 3050 Humlebaek, Denmark (612) 302-4922
Company Contact:	Tim Crabtree Regulatory Affairs Manager
Date Prepared:	June 14, 2011
Device Name:	Supris® Retropubic Sling System
Common Name:	Surgical mesh
Classification Name:	Surgical mesh, polymeric
Classification:	21 CFR §878.3300
Product Code:	OTN, FTL
Predicate Devices:	Mentor Aris™ Suprapubic Surgical Kit K053296

Description of Device: The *Supris* Retropubic Sling System is a permanent, synthetic sub-urethral sling that is provided with disposable needles in the system. The *Supris* sling is made from knitted monofilament polypropylene and has low elasticity. This structure gives the Supris sling resistance to traction, allows for tissue colonization and facilitates positioning during surgery.

Intended Use: The *Supris* Retropubic Sling System is an implantable, sub-urethral, support tape indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The sling is placed retropubically using two disposable introducers using either a "top down" or "bottom up" surgical approach

Purpose of Submission: Name change and labeling update with the description of bottom-up approach surgical approach.

Comparison of Surgical Approaches: The Supris Retropubic Sling System has not been evaluated in any clinical trial to compare the safety and effectiveness of the top-down vs. the bottom-up surgical approaches. The safety and effectiveness of both the top-down and the bottom-up approaches were evaluated based on a review of published scientific literature on other tension-free retropubic female urinary incontinence slings. The results of this review determined that both approaches are comparable in terms of risks and the occurrence of related adverse events. Additionally, the literature also cited that that either approach is used based on surgeon preference and medical specialty.

Substantial Equivalence: The changes cited in this submission do not affect substantial equivalence established in the original submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
Mr. Tim Crabtree
Regulatory Affairs Manager
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1601 West River Road North
MINNEAPOLIS MN 55411

JUN 24 2011

Re: K111233
Trade Name: SUPRIS® Retropubic Sling System
Regulation Number: 21 CFR §878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product code: OTN
Dated: June 14, 2011
Received: June 15, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
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): K111233

Device Name: Supris® Sling System

Indications for Use: The *Supris* Retropubic Sling System is an implantable, sub-urethral, support tape indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The sling is placed retropubically using two disposable introducers using either a "top down" or "bottom up" surgical approach

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 K111233