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MAY - 8 2009

K083099

6. 510(K) SUMMARY

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
Phone/Fax/Email:	Office: (612) 287-4211 Mobile: (651) 387-1698 Fax: (612) 287-4138 usjco@coloplast.com
Name Of Contact Person:	Janell A. Colley Regulatory Affairs Manager
Date Prepared:	November 24, 2008
Trade Or Proprietary Name:	Exair Anterior and Exair Posterior Prolapse Repair Systems
Common Or Usual Name:	Surgical mesh
Classification Name: CFR section 878.3300)	Surgical Mesh, polymeric

Legally Marketed Device To Which Your Firm Is Claiming Equivalence:

The Coloplast Exair Anterior and Exair Posterior Prolapse Repair Systems are substantially equivalent in performance, indications, design and materials to Coloplast's (formerly Mentor) NovaSilk Mesh, cleared under premarket notification number K053414 on 27 December 2005, and Ethicon Inc. Gynecare Prolift Total Pelvic Floor Repair System, cleared under Premarket notification number K071512 on 15 May 2008.

Device Description:

The Exair Anterior Prolapse Repair System is made of NovaSilk mesh precut into a shape with an enlarged body and four appendages extending out from the main body. The Exair Posterior Prolapse Repair System is made of NovaSilk mesh precut into a shape with an elongated body and two appendages extending out from the main body. The mesh arms for both Exair Anterior and Exair Posterior Prolapse Repair Systems are sleeved in 2-mil thick polyethylene to facilitate device arm implantation and positioning; sleeves are removed after proper

placement of implant is achieved. The System instrumentation includes a hollow introducer used to create a passage through the tissues and facilitate placement of the mesh arms, and four (4) anterior or two (2) posterior retrievers used to guide the mesh arms into place through the tissues for positioning and fixating the mesh body. The System is provided sterile and for single use only.

Intended Use Of The Device:

The Coloplast Exair Anterior and Posterior Prolapse Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Technological Characteristics Compared To Predicate Device:

The Coloplast Exair Anterior and Posterior Prolapse Repair Systems are substantially equivalent in design, materials, performance characteristics, and indications to the predicates Coloplast (formerly Mentor) NovaSilk Mesh, cleared under premarket notification number K053414 on 27 December 2005, and Gynecare Prolift Total Pelvic Floor Repair System, cleared under Premarket notification number K071512 on 15 May 2008.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence is supported by bench testing comparing Exair to the predicate devices and biocompatibility testing performed on the Exair device and instrumentation.

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

Coloplast A/S
% Ms. Janell A. Colley
Regulatory Affairs Manager
1499 West River Road North
MINNEAPOLIS MN 55411

SEP - 2 8 2012

Re: K083499
Trade/Device Name: Exair Anterior & Posterior Prolapse Repair Systems
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: May 1, 2009
Received: May 4, 2009

Dear Ms. Colley:

This letter corrects our substantially equivalent letter of May 8, 2009.

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

Coloplast

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K083499

Statement of Indications for Use

510(k) Number: K083499

Device Name: Exair Anterior & Posterior Prolapse Repair Systems

Indications for Use:

The Coloplast Exair Anterior and Posterior prolapse repair systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use (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 MXM

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

510(k) Number K083499