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510(K) SUMMARY

MAY - 8 2012

Ophira™ Mini Sling System

Submitter's name and address:

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Contact person and telephone number:

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Quality Assurance and Regulatory Affairs Manager
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Date Summary was prepared:

February 11, 2011

Name of the device:

Proprietary Name:	Ophira™
Common Name:	Mini Sling System
Classification Name:	Mesh, Surgical (21 CFR 878.3300)
Product Code:	OTN

Substantial Equivalence:

Ophira™ Mini Sling System is substantially equivalent in function and intended use to MiniArc Precise™ Single-Incision Sling, which has been cleared under K100807.

Device Description:

Ophira™ Mini Sling System consists of a sterile polypropylene sling and a sterile retractable insertion guide for sling placement. The sling is composed of monofilament polypropylene mesh between two polypropylene fixation arms; the fixation arms have multiple fixation points along the arms, which is the basis of the autofixing system, i.e., the two fixation arms are self anchored to the internus transobturator muscle and, therefore, the sling needs no sutures. An easily identifiable mark in the center of the mesh sling helps to achieve a symmetrically centered location for the proper placement of the sling. The sling has a suture inserted onto each fixation arm to provide the ability to adjust tension, if necessary, during the procedure for optimum suburethral support. These sutures are removed once the implantation procedure is completed.

Intended Use:

Ophira™ Mini Sling is intended to be used for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

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

Promedon S.A.
% Ms. Stephanie D. Rais
Consultant
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221 Ellis Parkway
PISCATAWAY NJ 08854

MAY - 8 2012

Re: K110420
Trade/Device Name: Ophira™ Mini Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: April 25, 2012
Received: April 26, 2012

Dear Ms. Rais:

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

K110420

Indications for Use Form

Indications for Use

510(k) Number (if known): ~~Unknown~~ K110420

Device Name: Ophira™ Mini Sling System

Indications for Use: Ophira™ Mini Sling System is intended to be used for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

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 K110420