K123479

DEC 1 1 2012

510(K) SUMMARY

This 510(k) summary of information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Submitter Information

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Establishment Registration:	9615742
Name of contact person:	James McMahon (US Agent) Associate Director, Regulatory Affairs Covidien 15 Hampshire Street Mansfield, MA 02048 USA Phone: 508-452-1545
Date prepared:	December 4, 2012

Name of device

Trade or proprietary name:	PROGRIP™ Laparoscopic Self-fixating Mesh
Common or usual name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric

Classification panel: General and Plastic Surgery (79)

Regulation: 21 CFR 878.3300

Product Code: FTL

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Legally marketed devices to which equivalence is claimed: PROGRIP™ Laparoscopic Self-Fixating Mesh (K120897)

Reason for 510(k) Submission: To propose the removal of a final product specification (lower specification of extractible pH). This change is supported by a final product specification (gripping points test). The combination of the upper extractible pH and the lot release final product specification (gripping point test) ensure the product effectiveness for intended use. This change does not impact the intended use and does not alter the fundamental scientific technology of the device.

Device description: The PROGRIP™ Laparoscopic Self-Fixating Mesh is available in anatomical and rectangular shapes.

The mesh is made of knitted monofilament polyester with monofilament polylactic acid resorbable grips on one side and a resorbable collagen film on the other side. The film is made up of collagen from porcine origin and glycerol. The grips allow positioning and fixation of mesh to the surrounding tissue, while the collagen film facilitates mesh handling and deployment. The mesh presents a green band that facilitates mesh orientation No changes to product have been made in this submission.

Intended use of the device: The PROGRIP™ Laparoscopic Self-Fixating Mesh is used for the reinforcement of tissues during surgical repair. No changes to the intended use have been made in this submission

Indications for use: PROGRIP™ Laparoscopic Self-Fixating Mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach. No changes to the indication for use have been made in this submission

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Summary comparing the technological characteristics of the subject and predicate devices:

The subject PROGRIP™ Laparoscopic Self-Fixating Mesh is identical to the predicate device PROGRIP™ Laparoscopic Self-Fixating Mesh (K120897) in terms of its physical, technological characteristics and performance characteristics.

The proposed and predicate (K120897) PROGRIP™ Laparoscopic Self-Fixating Mesh is a monofilament polyester knit with monofilament polylactic acid resorbable grips on one of the sides. The grips allow positioning and fixation of the mesh to surrounding tissue.

Performance data:

The removal of the collagen film lower specification of extractible pH, as a final product specification, does not affect the product performance. The combination of the upper extractible pH and the lot release final product specification (gripping point test) ensure the product effectiveness for intended use.

The change in specification does not alter the performance specifications of the PROGRIP™ Laparoscopic Self-Fixating Mesh (K120897) and does not require additional performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Sofradim Production
% Covidien LLC, Soft Tissue Implants
Mr. James McMahon
Associate Director, Regulatory Affairs
15 Crosby Drive
Bedford, Massachusetts 01730

December 11, 2012

Re: K123479
Trade/Device Name: PROGRIP™ Laparoscopic Self-Fixating Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 09, 2012
Received: November 19, 2012

Dear Mr. McMahon:

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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K123479

Device Name: PROGRIP™ Laparoscopic Self-Fixating Mesh

Indications for Use:

PROGRIP™ Laparoscopic Self-Fixating Mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach.

Prescription Use __X__ AND/OR Over-the -Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123479