510(k) Summary

July 13, 2012

Cook Biotech Incorporated

Surgisis® Staple Line Reinforcement

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Surgisis® Staple Line Reinforcement
Common Name:	Surgical mesh, collagen, staple line reinforcement Mesh, surgical, non-synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed
Classification Regulations:	Class II, 21 CFR §878.3300 (OXE, PAJ)

INTENDED USE:

The Surgisis Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (*e.g.*, wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repair, muscle flap reinforcement, trans-abdominal rectal and vaginal prolapse repair, trans-abdominal reconstruction of the pelvic floor, and repair of hernias (*e.g.*, diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The Surgisis® Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers. The device is supplied sterile and is intended for one-time use.

PREDICATE DEVICES:
The Surgisis Staple Line Reinforcement is similar to predicate devices, including the Surgisis® Soft Tissue Graft (K980431) and Surgisis® Peripheral Vascular Patch (K001785) manufactured by Cook Biotech Incorporated, the Peri-Strips® Staple Line Reinforcement-Strip (K983162) manufactured by Biovascular Incorporated, and the Seamguard® Staple Line Reinforcement Material (K010936) manufactured by W.L. Gore & Associates.

DEVICE DESCRIPTION:

The Surgisis Staple Line Reinforcement is manufactured from porcine small intestinal submucosa and supplied in nominal strip sizes (unfolded) of 1 x 10.7 cm, 1.2 x 13.2 cm, and 1.2 x 17.3 cm. The device is packaged sterile, sealed double pouches.

SUBSTANTIAL EQUIVALENCE TO MARKETED DEVICES

The Surgisis Staple Line Reinforcement is similar with respect to intended use, materials and technological characteristics to the predicate device in terms of section 510(k) substantial equivalence, as shown biocompatibility testing (conducted in accordance to ISO 10993-1 standards), mechanical and clinical testing.

DISCUSSION OF TESTS AND TEST RESULTS:
The material comprising the Surgisis Staple Line Reinforcement was subjected to a panel of tests to assess biocompatibility, disinfection, and performance characteristics. The material met the test requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

CONCLUSIONS DRAWN FROM THE TESTS:
The Surgisis Staple Line Reinforcement is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

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

Cook Biotech, Incorporated
% Mr. Mark Bleyer
President
3055 Kent Avenue
West Lafayette, Indiana 47906-1076

AUG 30 2012

Re: K022044
Trade/Device Name: Surgisis® Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXE, FTM, PAJ
Dated: June 20, 2002
Received: June 24, 2002

Dear Mr. Bleyer:

This letter corrects our substantially equivalent letter of August 23, 2002.

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" (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,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Surgisis® Staple Line Reinforcement**

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The device is supplied sterile and is intended for one-time use.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K022044