

K992159: Surgisis® Sling

510(k) Summary

September 11, 2013

Cook Biotech Incorporated

Surgisis® Sling

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® Sling
Common Name: Surgical mesh
Classification Regulations: Class II, 21 CFR §878.3300
Product Code: PAG, PAJ, FTM

INTENDED USE:

The Surgisis® Sling is intended for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

PREDICATE DEVICES:

Surgisis® Mesh (K980431) manufactured by Cook Biotech Incorporated
Glycar Staple Strips (K954665) manufactured by Glycar, Incorporated
Mentor Suspend™ Sling (K980483) manufactured by Mentor Corporation
Surgical Fabrics (K963226) manufactured by Boston Scientific

DEVICE DESCRIPTION:

The Surgisis® Sling is supplied in sheet form in sizes ranging from 20 cm² to 140 cm². The device is packaged in sterile, sealed double pouches.

K992159: Surgisis® Sling

SUBSTANTIAL EQUIVALENCE TO MARKETED DEVICES

The Surgisis® Sling is substantially equivalent to the predicate devices, having the same intended use and technological characteristics.

DISCUSSION OF TESTS AND TEST RESULTS:

The Surgisis® Sling was subjected to a panel of tests to assess biocompatibility, integrity, and performance. The Surgisis® Sling passed the requirements of all tests.

CONCLUSIONS DRAWN FROM THE TESTS:

The device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Cook Biotech Incorporated
% Neal E. Fearnot, Ph.D.
President
3055 Kent Avenue
West Lafayette, IN 47906

Re: K992159
Trade/Device Name: Surgisis® Sling
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: PAG, PAJ, FTM
Dated (Date on orig SE ltr): June 23, 1999
Received (Date on orig SE ltr): June 25, 1999

Dear Neal E. Fearnot, Ph.D.,

This letter corrects our substantially equivalent letter of September 23, 1999.

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 contact 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>. 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 -S

for

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

Indications for Use

510(k) Number (if known): K992159

Device Name: Surgisis® Sling

Indications For Use:

The Surgisis® Sling is intended for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

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

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

Herbert P. Lerner -S