JUL 2 3 2014

510(k) Summary

July 18, 2014

Cook Biotech Incorporated

SIS Hernia Graft

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:	SIS Hernia Graft
Common Name:	Surgical graft
Classification Regulations:	Class II, 21 CFR §878.3300 (FTM and OXK)

INDICATIONS FOR USE:

The SIS Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include repair of a hernia or body wall defect. The graft is supplied sterile and intended for one time only use.

DEVICE DESCRIPTION:

The SIS Hernia Graft is composed of multiple layers of a bioabsorbable, extracellular collagen membrane matrix (Small Intestinal Submucosa, SIS) that are held together with a biodegradable suture to improve the device handling characteristics at time of implant. The SIS Hernia Graft is identical in its base material to its predicate SIS Hernia Repair Device (K974540/K062697), also manufactured by Cook Biotech Incorporated.

The SIS Hernia Graft is substantially equivalent to its predicate in its technology in that it has the ability to be incorporated into the body. The device is substantially equivalent to its predicate in its intended use for reinforcement and repair of hernias or a body wall defect. The device is packaged in a dried state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The SIS Hernia Graft is substantially equivalent with respect to intended use, materials and technological characteristics to its predicate device in terms of section 510(k) substantial equivalence, as shown in biocompatibility testing (conducted in accordance to ISO 10993-1 standards), mechanical and pre-clinical testing.

Biocompatibility testing

The following biocompatibility tests were performed on sterilized SIS devices, which are identical in base material composition to the SIS Hernia Graft (according to the ISO 10993-1 standard):

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- Skin irritation
- ISO Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

The results of these tests provided evidence that the SIS Hernia Graft meets biocompatibility requirements of the ISO standard.

Mechanical Testing

The SIS Hernia Graft material was tested for the following:

- Suture retention strength
- Burst strength
- Ultimate tensile strength
- Tear strength
- Stiffness test

The results of the mechanical testing provided evidence that the SIS Hernia Graft provided adequate mechanical strength for its application.

Animal Testing

A study was performed where the SIS Hernia Graft was implanted in a pig hernia model and examined for gross and histopathological results after 27 days. The results show that the device is well tolerated with minimal localized tissue response. A second pig hernia study used the SIS Hernia Graft as a control article and examined one and 6-months post-implant showed satisfactory remodeling characteristics with minimal inflammation. Another animal study in the mouse examined the angiogenesis of the SIS Hernia Graft showed that the sutured SIS performed as well as its sutureless control SIS with robust vascular penetration. The results of the studies show that the device is safe and biocompatible in its application.

Substantial Equivalence

See Table 1 for a comparison of the subject device and its predicate.

Table 1 – Substantial Equivalence Comparison

Device	SIS Hernia Graft	SIS Hernia Repair Device	SIS Hernia Repair Device
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Cook Biotech Incorporated
510(k) Number	K133306	K974540	K062697
Intended Use	Intended for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.	Intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.	Intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.
Material	Porcine small intestinal submucosa (porcine) Primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)	Porcine small intestinal submucosa (porcine) Primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)	Porcine small intestinal submucosa (porcine) Primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)
Dimensions	5 x 8 cm to 30 x 30 cm	5 x 8 cm to 20 x 30 cm	1 x 3 to 20 x 30 cm
Thickness	0.1 – 1.5mm	0.1 – 1.5 mm	0.1 – 1.5 mm
Type of drying	Lyophilized	Vacuum pressed	Vacuum pressed
Layers	8 layers	8 layers	8 layers
Stitched (resorbable suture)	Yes	No	No
Biocompatible	Yes	Yes	Yes

While the SIS Hernia Graft is dried differently than the predicate SIS Hernia Repair Device, the SIS material is the same and exhibits similar incorporation and resorption characteristics when implanted. The suture stitching of the SIS Hernia Graft is intended to hold the layers of the device together during the implantation period and is resorbed without any effect on the SIS material.

CONCLUSION: The biocompatibility, mechanical, and animal tests performed on the SIS Hernia Graft show that the device is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 23, 2014

Cook Biotech Incorporated
Mr. Perry W. Guinn
Vice President, Quality Assurance and Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K133306
Trade/Device Name: SIS Hernia Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXK
Dated: June 10, 2014
Received: June 11, 2014

Dear Mr. Guinn:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133306

Device Name
SIS Hernia Graft

Indications for Use *(Describe)*
The SIS Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include repair of a hernia or body wall defect. The graft is supplied sterile and intended for one time only use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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