K133011

510(k) Summary

JUN 2 0 2014

June 19, 2014

Cook Biotech Incorporated

Diaphragmatic 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:	Diaphragmatic Hernia Graft
Common Name:	Surgical mesh
Classification Regulations:	Class II, 21 CFR §878.3300 (FTM)

INTENDED USE:

The Diaphragmatic Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists, including the repair of diaphragmatic/hiatal hernias. The graft is supplied sterile and intended for one time use.

DEVICE DESCRIPTION:

The Diaphragmatic 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 the time of implant. The Diaphragmatic Hernia Graft is identical in its base material to its predicates SIS Hernia Repair Device (K974540/K062697) and Surgisis Staple Line Reinforcement (K022044), also manufactured by Cook Biotech Incorporated, and similar to its predicate Permacol™ Surgical Implant (K120605), manufactured by Covidien.

The Diaphragmatic Hernia Graft is substantially equivalent to its SIS predicates in that its technology is able to be incorporated into the body. The device is also substantially equivalent to its predicates in its intended use for reinforcement and repair of diaphragmatic/hiatal hernias. The device is packaged in a dried state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

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

Biocompatibility Testing

The following biocompatibility tests were performed on sterilized SIS devices, which are identical in base material to the Diaphragmatic 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 Diaphragmatic Hernia Graft meets biocompatibility requirements of the ISO standard.

Mechanical Testing

The Diaphragmatic Hernia Graft material was tested for the following:

- Suture retention strength
- Burst strength
- Tensile strength
- Stiffness

The results of the mechanical testing provide evidence that the Diaphragmatic Hernia Graft possesses adequate mechanical strength for its application.

Animal Testing

The SIS material that comprises the Diaphragmatic Hernia Graft has been tested in animal studies for diaphragmatic/hiatal hernia repair. These animal studies provide evidence that the Diaphragmatic Hernia Graft is biocompatible and safe in its application.

Clinical Testing

The performance of Surgisis (which is made of SIS, the same base material as the Diaphragmatic Hernia Graft) was assessed in several different clinical studies. The clinical outcomes of these studies show that the SIS material, which comprises the Diaphragmatic Hernia Graft, is safe and biocompatible. Further clinical evidence was submitted showing that the rectangular flat sheet and U-shape configurations of the Diaphragmatic Hernia Graft performed adequately in patients. These studies provide evidence that the Diaphragmatic Hernia Graft is substantially equivalent to its predicates in this application.

Substantial Equivalence

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

Table 1 – Substantial Equivalence Comparison

Device	Diaphragmatic Hernia Graft	SIS Hernia Repair Device	Surgisis Staple Line Reinforcement	Permacol Surgical Implant
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Cook Biotech Incorporated	Covidien
510(k) Number	K133011	K974540/K062697	K022044	K120605
Intended Use	For implantation to reinforce soft tissues where weakness exists, including the repair of diaphragmatic/hiatal hernias.	To be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.	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, segmenteectomy, 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	Intended for use as a soft tissue implant to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, incisional, parastomal hernias and abdominal wall defects.

Device	Diaphragmatic Hernia Graft	SIS Hernia Repair Device	Surgisis Staple Line Reinforcement	Permacol Surgical Implant
			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.	
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)	Porcine dermis (collagen)
Dimensions	Nominally, 7 x 10 cm (a rectangular flat sheet configuration and a U shaped configuration). The rectangular sheet has resorbable stitching across the graft and the U-shape graft is stitched on the edges to reduce delamination during implantation	5 x 8 cm to 20 x 30 cm	1.0 x 3.8 cm to 1.2 x 8.8 cm	1 cm x 4 cm to 28cm x 40 cm
Thickness	0.1 – 1.5mm	0.1 – 1.5 mm	0.350 mm	0.5-1.5 mm

CONCLUSION: The biocompatibility, mechanical, pre-clinical and clinical tests performed on the Diaphragmatic Hernia Graft show that the device is substantially equivalent to its predicates.

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

June 20, 2014

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

Re: K133011
Trade/Device Name: Diaphragmatic Hernia Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWV, FTM
Dated: May 20, 2014
Received: May 21, 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)*
K133011

Device Name
Diaphragmatic Hernia Graft

Indications for Use *(Describe)*
The Diaphragmatic Hernia Graft is intended for implantation to reinforce soft tissue where weakness exists, including the repair of diaphragmatic/hiatal hernias. The graft is supplied sterile and intended for one time 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
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