



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

July 10, 2017

Cook Biotech Incorporated
Ms. Daniela Changkuon
Regulatory Affairs Specialist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K162934

Trade/Device Name: Biodesign Parastomal Hernia Repair Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXK
Dated: June 7, 2017
Received: June 12, 2017

Dear Ms. Changkuon:

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" (21 CFR 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,

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

Indications for Use

510(k) Number (if known)

K162934

Device Name

Biodesign Parastomal Hernia Repair Graft

Indications for Use (Describe)

The Biodesign Parastomal Hernia Repair Graft is intended for use as a soft tissue patch where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906

Phone: (765) 497-3355

Contact Person: Perry W. Guinn
Date Prepared: 05 June 2017

II. DEVICE

Name of Device:	Biodesign® Parastomal Hernia Repair Graft
Common or Usual Name:	Surgical graft
Classification Name:	Mesh, Surgical (21 CFR §878.3300)
Regulatory Class:	II
Product Code:	FTM, OXK

III. PREDICATE DEVICE

Permacol® Surgical Implant (K043366; Medtronic)

Reference Device: SIS Hernia Graft (K133306, Cook Biotech Incorporated)

IV. DEVICE DESCRIPTION

The Biodesign® Parastomal Hernia Repair Graft is identical to the SIS Hernia Graft (i.e. same raw materials, manufacturing processes, configuration, packaging and sterilization). The devices are composed of multiple layers of porcine Small Intestinal Submucosa (SIS), a bioabsorbable, extracellular collagen matrix (ECM) that is non-crosslinked and decellularized; additionally, the device is held together with biodegradable suture to improve device handling characteristics at time of implant and is perforated to assist with fluid transfer. The single-use devices are packaged in a dried state and supplied sterile (EtO) in a sealed double pouch system.

V. INDICATIONS FOR USE

The Biodesign® Parastomal Hernia Repair Graft is intended for use as a soft tissue patch 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 wall defects and hernias, including but not limited to parastomal hernias.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Biodesign® Parastomal Hernia Repair Graft is substantially equivalent to its predicate in that they are both specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias. The technological principle for both the subject and predicate devices is mechanical reinforcement of soft tissue without leaving behind long-term foreign materials. The two devices are biological scaffolds derived from porcine tissue that are processed and designed to meet the requirements of the intended clinical use. Both devices undergo a remodeling process whereby the scaffold is eventually completely replaced by host tissue.

The predicate device is composed of porcine dermis (predominantly collagen and elastin fibers) which is cross-linked by hexamethylene diisocyanate (HMDI). The subject device is composed of non-crosslinked porcine SIS and biodegradable suture; the Biodesign® Parastomal Hernia Repair Graft is identical in all aspects to the SIS Hernia Graft (K133306; reference device). **Table 5-1** below provides a comparison of the subject, predicate and reference devices.

Table 5-1. Substantial Equivalence Information

Device	Biodesign® Parastomal Hernia Repair Graft	Permacol® Surgical Implant	SIS Hernia Repair Graft (reference device)
Manufacturer	Cook Biotech Inc.	Medtronic	Cook Biotech Inc.
510 (k) Number	K162934	K043366	K133306
Intended Use	Intended for use as a soft tissue patch 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 wall defects and hernias, including but not limited to parastomal hernias.	Intended for use as a soft tissue patch 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 wall defects and hernias, including but not limited to parastomal hernias.	Intended for implantation to reinforce soft tissue where weakness exists. Indications for use include repair of a hernia or body wall defect.
Product Code	FTM, OXK	FTL	FTM, OXK

Device	Biodesign® Parastomal Hernia Repair Graft	Permacol® Surgical Implant	SIS Hernia Repair Graft (reference device)
Material	Porcine small intestinal submucosa (extracellular matrix - primarily collagen types I, III, IV and VI) and polyglycolic acid (PGA) sutures	Porcine dermis (extracellular matrix - primarily collagen and elastin).	Porcine small intestinal submucosa (extracellular matrix - primarily collagen types I, III, IV and VI) and polyglycolic acid (PGA) sutures
Crosslinking	Non-crosslinked	Crosslinked (HMDI)	Non-crosslinked
Dimensions	5 cm x 8 cm to 30 x 30 cm	1 cm x 4 cm to 28 cm x 40 cm	5 cm x 8 cm to 30 x 30 cm
Thickness	0.1 mm to 1.5 mm	0.5 mm to 1.5 mm	0.1 mm to 1.5 mm
Sterilization	ethylene oxide	gamma irradiation	ethylene oxide
One-time Use	Yes	Yes	Yes

VII. PERFORMANCE DATA

Biocompatibility:

The Biodesign® Parastomal Hernia Repair Graft is identical to the SIS Hernia Graft (i.e. same raw materials, manufacturing processes, configuration, packaging and sterilization). The following biocompatibility tests were performed on finished devices in accordance with the FDA's biocompatibility testing guidance *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* (May 1, 1995):

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

Testing results show that the Biodesign® Parastomal Hernia Repair Graft meets all biocompatibility requirements of the ISO standard for permanent implantable devices.

Product characterization - Mechanical:

The Biodesign® Parastomal Hernia Repair Graft is identical to the SIS Hernia Graft (i.e. same raw materials, manufacturing processes, configuration, packaging and sterilization). Mechanical testing was performed on finished devices to evaluate the mechanical performance of the device for its intended use. The following mechanical tests were performed in accordance with FDA's *'Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh'* (March 2, 1999):

- Burst strength
- Ultimate tensile strength
- Device stiffness
- Suture retention strength
- Tear strength
- Delamination

Product characterization testing shows that the Biodesign® Parastomal Hernia Repair Graft provides adequate mechanical strength for use in the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.

Safety and Performance - Clinical Data:

Clinical data to support the safety and performance of the Biodesign® Parastomal Hernia Repair Graft material for the surgical repair of abdominal wall defects and hernias, including parastomal hernias, is primarily in the form of peer-reviewed publications. The literature describes the safe and effective use of SIS-based devices to treat soft tissue deficiencies in the parastomal anatomy. **Table 5-2** summarizes the results of a study published by Ellis^A using SIS for the repair of parastomal hernias.

Table 5-2. Surgical outcomes with the use of SIS for parastomal hernias

Study	Number of Patients	Follow-up	Recurrence	Graft-Related Complications	Comments
Ellis ^A	20	Median: 18 months; Range: 6-38 months	Two (2) recurrent parastomal hernias identified (10%)	There were four (4) seromas in the initial 10 patients. Drains were then routinely placed in the final 12 procedures and no additional seromas were reported.	Both recurrences were identified in patients with complicated cases – one with 12 previous repair attempts and removal of infected mesh, and one, in a patient with a 12 cm fascial defect. Although the initial repair with SIS failed, both patients were doing well (at 36 and 14 months) following a second repair procedure with an SIS graft.

Unpublished long term data on 19/20 patients (same patient cohort described above – four patients died of cancer, unrelated to their procedures) confirms, by physical or radiological (CT) examination, that the SIS-based devices perform as intended at a median follow-up time of 53 months (range 29-69 months). Three additional recurrences were identified, bringing the total recurrence rate to 25% (5/20 patients). Of the three recurrences diagnosed, two were asymptomatic and did not require additional surgical management at 58 and 47 month follow-up. The last recurrence occurred in a patient where an SIS graft was used to bridge the defect. After a second repair procedure with SIS, no recurrence was detected at 63 month follow-up. No other complications were reported.

VIII. CONCLUSIONS

For purposes of determinations of substantial equivalence under *section 513(i) of the FD&C Act (21 U.S.C. § 360c(i))*, the Biodesign® Parastomal Hernia Repair Graft has the same intended use and functions under the same technological principle as the predicate device. The subject and predicate device are both porcine-derived scaffolds designed to provide mechanical reinforcement of soft tissues where weakness exists, while

^A Ellis CN. Short-term outcomes with the use of bioprosthesis for the management of parastomal hernias. *Diseases of the Colon and Rectum*. 2010;53(3):279-283.

simultaneously being remodeled and replaced with host tissue. The main technological differences between the subject device and the predicate device are that the Biodesign[®] Parastomal Hernia Repair Graft is composed of non-crosslinked SIS and the predicate device is composed of crosslinked dermal collagen.

. The biocompatibility tests, product characterization tests, and clinical data on the Biodesign[®] Parastomal Hernia Repair Graft demonstrate that the device is substantially equivalent to the predicate device.