DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

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

Re: K170945
Trade/Device Name: Biodesign Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXE, FTM
Dated: March 28, 2017
Received: March 30, 2017

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" (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

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)*

Device Name
Biodesign Staple Line Reinforcement

Indications for Use *(Describe)*
The SURGISIS SLR 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 bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers.

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.

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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: 28 March 2017

II. DEVICE

Name of Device:	Biodesign® Staple Line Reinforcement
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh
Product Code:	FTM (21 CFR §878.3300), OXE
Regulatory Class:	Class II

III. PREDICATE DEVICE

SURGISIS® SLR™ Staple Line Reinforcement (K070405, Cook Biotech Incorporated)

IV. DEVICE DESCRIPTION

The Biodesign® Staple Line Reinforcement device is part of a family of implant devices manufactured from porcine small intestine that are disinfected and processed to remove the tunica mucosa from the inner intestinal surface and the serosa and tunica muscularis from the outer intestinal surface. The resulting membrane is a three dimensional, acellular, collagen-rich extracellular matrix (ECM) that is termed small intestinal submucosa (SIS). Biodesign® Staple Line Reinforcement consists of a thin multi-layer strip of SIS, pre-coated with an adhesive that eliminates the need for a separate adhesive (e.g. hydrogel) to affix the device to surgical stapler jaws. The single-use device is provided on a foam applicator and suspended in a form-fitting tray before being sealed in a foil pouch and sterilized (E-beam). The material composition, general manufacturing processes, packaging configuration and sterilization method of the subject device are identical to the predicate, SURGISIS® SLR™ Staple Line Reinforcement (K070405).

Upon implantation, the Biodesign® Staple Line Reinforcement device will provide mechanical reinforcement of the staple line by buttressing the soft tissue and preventing the surgical staples from tearing through the affected tissue. In addition, the Biodesign® Staple Line Reinforcement device will incorporate (remodel) into the body over time such that no graft material is left behind.

V. INDICATIONS FOR USE

The Biodesign® 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 bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Biodesign® Staple Line Reinforcement device is identical to its predicate in that they are both intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. Moreover, the subject device’s component materials, general manufacturing processes, fundamental scientific technology, and mode of action remain unchanged from the predicate.

The only modification to the Biodesign® Staple Line Reinforcement devices is the addition of thinner configurations (dimensional change) to the already existing line of staple line reinforcement devices. **Table 5-1** provides a comparison of the subject and predicate devices.

Table 5-1. Substantial Equivalence Information

Device	Biodesign® Staple Line Reinforcement (subject device)	SURGISIS® SLR™ Staple Line Reinforcement (predicate device)
Manufacturer	Cook Biotech, Inc.	Cook Biotech, Inc.
510 (k) Number	Not assigned	K070405
Product Code	FTM	FTM
Intended Use	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 bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers.	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 bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers.
Materials and Components	SIS buttressing strip Pre-coated adhesive Polystyrene foam applicator	SIS buttressing strip Pre-coated adhesive Polystyrene foam applicator
SIS Device Dimensions (unfolded)	Length: 76 mm to 176 mm Width: 10 mm to 12 mm Thickness: 4-layer SIS (100 µm to 500 µm) 2-layer SIS (50 µm to 300 µm)	Length: 76 mm to 176 mm Width: 10 mm to 12 mm Thickness: 4-layer SIS (100 µm to 500 µm)
Shelf-Life	18 months	18 months
Packaging	foil pouch	foil pouch
Sterilization	E-beam	E-beam
One-time Use	Yes	Yes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the predicate device has been established in accordance with ISO 10993-1:2009 – *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* to demonstrate that the device is safe for permanent contact (>30 days) implantation. The predicate test data was leveraged to support the substantial equivalence of the subject device as the device materials and general manufacturing processes are identical for the subject and predicate devices.

Non-Clinical testing

Product verification testing was performed on sterilized finished devices to evaluate the mechanical performance of the subject device for its intended use. Staple line leakage testing confirms that the Biodesign® Staple Line Reinforcement provides adequate staple line buttressing for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers.

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® Staple Line Reinforcement device has the same intended use and functions under the same mode of action and fundamental scientific technology as the predicate device. In addition, the subject device is composed of the same materials and manufactured using the same processes as the predicate. The only design modification is with regard to device dimensions, where the subject device includes thinner configurations to supplement the existing line of SIS staple line reinforcement devices. The absence of changes in the fundamental scientific technology and intended use of the device, as well as a risk analysis and completion of verification and validation activities, provide evidence to support the conclusion that the thickness modification does not introduce new risks and that the subject device performs comparably to the predicate device that is currently marketed for the same intended use.