DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 21, 2017

Cook Biotech Incorporated
Nick Wang, Ph.D., RAC
Regulatory Affairs Scientist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K170016
Trade/Device Name: Biodesign Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: May 24, 2017
Received: May 25, 2017

Dear Dr. Wang:

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)*

K170016

Device Name
Biodesign® Fistula Plug

Indications for Use *(Describe)*
The Biodesign® Fistula Plug is for implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas.

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.

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510(k) Summary

Submitted By: Perry W. Guinn
Vice President of Quality Assurance & Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
December 30th, 2016

Name of Device:

Trade/Proprietary Name:	Biodesign® Fistula Plug
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh (21 CFR 878.3300, Product Code: FTM)
Device Class:	Class II

Predicate Device:

SIS Fistula Plug (K050337, Cook Biotech Inc.)

Reference Devices:

Modified Fistula Plug (K062729, Cook Biotech Inc.)

Intended Use:

The Biodesign® Fistula Plug is for implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas.

General Description of Clinical Condition:

Anorectal and recto-vaginal fistulas are unnatural tracts connecting the anal canal to either the perianal skin (anorectal) or the vagina (recto-vaginal). First line treatment strategies typically involve conservative management of symptoms and allowing the fistula to heal. If the fistula persists, surgical repair is usually performed. Less invasive treatment options (e.g., plugs) are frequently pursued as initial treatment strategies before more invasive procedures are considered. Fistula plugs made from porcine small intestinal submucosa (SIS), which include the predicate and subject devices, are one such less invasive treatment option.

Device Description:

The Biodesign® Fistula Plug is a fistula repair device made from porcine SIS, a collagen rich, bioresorbable, extracellular matrix (ECM)-based biomaterial. The device design consists of a tapered SIS cylinder (plug body) and an SIS flange/button connected together using biodegradable polyglycolic acid (PGA) surgical suture. The function of the plug body is to fill the fistula tract and the function of the flange/button is to anchor the device at the internal fistula opening. Three different size offerings (2mm, 5mm and 7mm) are available based on the diameter of the primary end of the plug.

Comparison to Predicate Device:

The subject and predicates devices have the same general intended use (to reinforce soft tissue for the repair of fistulas), but have slightly different indication statements. The indication statement of the subject device has been modified to more accurately describe the disease or condition the subject device is designed to treat; the modified indication statement does not imply a new or different intended use.

The subject and predicate devices share the same fundamental technology: the use of shaped SIS plugs to reinforce soft tissue for the repair of fistulas. The main difference between the subject and predicate is the addition of a SIS flange/button on the subject device. The added flange/button is intended to help secure the plug in place once it is implanted (a similar flange/button is in the cleared reference device). The design difference does not alter the fundamental mechanism of action as both devices still use the same SIS plug body for the repair of fistulas.

Summary of Non-Clinical Tests:

The following testing was performed to demonstrate substantial equivalence:

- Biocompatibility testing was performed on SIS and PGA suture:
  - Cytotoxicity
  - Sensitization
  - Irritation/Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Subchronic Toxicity
  - Genotoxicity
  - Implantation
- Performance Testing - Bench
  - Extrusion resistance testing
  - Tensile strength testing
  - Plug suture retention strength

The results of the testing confirm that the subject device does not pose new or different biocompatibility risks and can withstand the expected mechanical forces on the device.

Substantial Equivalence:

Table 5-1 provides a comparison of the subject, reference and predicate devices.

To provide further evidence of substantial equivalence, CBI used the 510(k) Decision-Making Flowchart from the FDA guidance document *Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (July 28, 2014)* to compare and assess the intended use and the technological characteristics of the subject, reference and predicate devices. Specifically, the indication for use statements were compared and analyzed. CBI provided evidence that the new indication statement more accurately described the disease or condition the subject device is designed to treat; it did not confer a new or different intended use. In terms of technological characteristics, the subject device includes the addition of an SIS flange/button. The additional SIS flange/button does not change the fundamental technology, namely application of porcine SIS plug to reinforce soft tissue for fistula repair. A similar flange/button is part of the reference device design. CBI has performed non-clinical testing to ensure the differences between subject and predicate device do not raise new questions of safety or effectiveness. In conclusion, CBI believes the Biodesign® Fistula Plug is substantially equivalent to the SIS Fistula Plug based on the non-clinical performance testing and the identical nature of the fundamental technology.

Table 5-1. Substantial Equivalence Information

	Biodesign® Fistula Plug (Subject Device)	**SIS Fistula Plug (Predicate Device)**	**Modified Fistula Plug (Reference Device)**
510(k) number	unassigned	K050337	K062729
Indication for Use	For implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas.	For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas.	For implantation to reinforce soft tissue for repair of recto-vaginal fistulas.
Components/ Materials	• Porcine small intestinal submucosa plug • Porcine small intestinal submucosa flange/button • Polyglycolic acid suture	• Porcine small intestinal submucosa plug	• Porcine small intestinal submucosa plug • Polyetherimide flange/button • Polyglycolic acid suture
Dimensions	Length: 51 mm Diameter: 2 mm, 4 mm, 7 mm (tapered to 2 mm)	Length: 100 mm Diameter: 2 to 7 mm (7mm tapered to 2mm)	Length: 51 mm Diameter: 2 mm, 4 mm, 7 mm (tapered to 2 mm)
Technological Features	Includes a plug and a flange/button connected by PGA suture	Includes just a plug	Includes a plug and a flange/button connected by PGA suture
Supplied sterile?	Yes	Yes	Yes
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Intended for single use?	Yes	Yes	Yes