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

December 9, 2015

Cook Biotech Incorprated
Mr. Nick Wang
Regulatory Affairs Scientist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K150668
Trade/Device Name: Biodesign Enterocutaneous Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: March 13, 2015
Received: November 10, 2015

Dear Mr. 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 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)*
K150688

Device Name
Biodesign® Enterocutaneous Fistula Plug

Indications for Use *(Describe)*
The Biodesign® Enterocutaneous Fistula Plug is intended for implantation to reinforce soft tissue for repair of enterocutaneous fistulas. The device is supplied sterile and is 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)*

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

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510(k) Summary

13 March 2015

Cook Biotech Incorporated

Biodesign® Enterocutaneous Fistula Plug

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, VP of Quality Assurance and Regulatory Affairs

Device Name and Classification:

Trade Name:	Biodesign® Enterocutaneous Fistula Plug
Common/Usual Name:	Surgical Mesh
Proposed classification name:	Surgical Mesh 21 CFR 878.3300 (FTM) Class II

Indications for Use:

The Biodesign® Enterocutaneous Fistula Plug is intended for implantation to reinforce soft tissue for repair of enterocutaneous fistulas. The device is supplied sterile and is intended for one-time use.

Predicate Device:

The predicate device is the Surgisis® Biodesign® Enterocutaneous Fistula Plug (K082682), also manufactured by Cook Biotech Incorporated.

Device Description:

The Biodesign® Enterocutaneous Fistula Plug is a bioabsorbable, collagen-derived, minimally invasive treatment option for the repair of enterocutaneous fistulas. The device consists of two parts - an implanted device and a delivery system. The implanted device

has four components - the small intestinal submucosa (SIS) plug, the flange/gasket assembly, the suture tether and the Molnar Disc. The SIS plug is manufactured from porcine small intestine that has been stripped of its serosal, mucosal, and muscle layers and virally inactivated. The resulting acellular collagenous layer, termed Small Intestinal Submucosa, is manufactured into a rolled, freeze dried plug. The function of the SIS plug is to fill and aid in the healing of the tract. The plug fully remodels into patient tissue over time. The other three components, the flange/gasket assembly, the suture tether and the Molnar Disc are all temporary implants designed to either naturally pass out of the body or fall off the skin. The function of the flange/gasket assembly is to seal the internal opening of the fistula tract and prevent the ingress of any gastric/intestinal fluid from entering the fistula tract. The suture connects the flange assembly at the internal opening of the fistula to the Molnar Disc at the external opening. Tethering the suture to the Molnar Disc provides tension to keep the flange/gasket assembly securely in place. In addition to the implanted device, a delivery system is provided to ensure proper device delivery and deployment.

Equivalence of Market Device:

The Biodesign® Enterocutaneous Fistula Plug, the subject device, is a design improvement of the predicate device, Surgisis® Biodesign® Enterocutaneous Fistula Plug (K082682). The modifications described in this 510(k) are made based on user feedback and clinical experience resulting from use of the predicate device. Analysis and comparison of the intended use, and material and technological characteristics, in conjunction with relevant testing, support the determination that the subject and predicate devices are substantially equivalent. A brief summary of the relevant testing and the substantial equivalence comparison are provided below in this 510(k) summary.

Biocompatibility

The biocompatibility assessment of the Biodesign® Enterocutaneous Fistula Plug was conducted in accordance with FDA's biocompatibility testing guidance, *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* (May 1, 1995). Based on the standard, the plug, the flange/gasket assembly, the delivery system and the Molnar Disc each have different classifications. The classifications are summarized in Table 5-1.

Table 5-1. Biocompatibility Classification

Device Component	Biocompatibility Classification		
	Device Type	**Contact**	**Duration**
SIS Plug	Implant device	Tissue contacting	Permanent (>30 days)
Flange/gasket assembly	Surface device	Mucosal membrane contacting	Prolonged contact (24 hrs – 30 days)
Delivery device	Externally communicating device	Tissue contacting	Limited (<24 hrs)
Molnar Disc	Surface device	Skin contacting	Prolonged contact (24 hrs – 30 days)

Relevant biocompatibility testing was performed based the biocompatibility classification of each of the components.

For example, the following biocompatibility tests were performed on portions classified to be permanent tissue implant (e.g. the SIS material):

- Genotoxicity
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- Skin irritation
- ISO sensitization
- Acute systemic toxicity
- Subchronic systemic toxicity

The results of the biocompatibility assessment provided evidence that the Biodesign® Enterocutaneous Fistula Plug meets the biocompatibility requirements of the ISO-10993 standard.

Mechanical Testing

Mechanical testing was conducted to ensure the device design is appropriate and the device is able to function as intended. Tests performed include:

- Leak resistance
- Pushability
- Deployment
- Gasket expansion
- Leak resistance

- Tensile strength
- Two-plug deployment

The same types of testing were used to support the clearance of the predicate device (K082682). All testing were performed on terminally sterilized devices.

Animal Testing

A GLP animal study was performed using the Biodesign® Enterocutaneous Fistula Plug (subject device) in a domestic swine model. The purpose of the animal study was to characterize the safety and biological response of the Biodesign® Enterocutaneous Fistula Plug under a simulated use animal model. Endpoints of the study included evaluation of local, regional responses of the intestine and adjacent organs, as well as the time over which the flange portion of the device remained in the luminal surface of the intestine. The study showed closure of the surgically created fistulas, complete incorporation of enterocutaneous fistula plugs at five weeks, with no negative clinical sequelae.

Conclusions drawn from tests

Evaluation of the subject device, Biodesign® Enterocutaneous Fistula Plug, provides evidence of its suitability for use in soft tissue repair of enterocutaneous fistulas and substantial equivalency to the predicate device in terms of intended use, material, and technological characteristics.

Substantial Equivalence

All differences between the predicate and the subject device were analyzed; the differences did not change the intended use, fundamental mode of action, or introduce new types of questions in risks or effectiveness, thus supporting a determination that the subject and predicate devices are substantially equivalent. See Table 5-2 below for a comparison of the subject and predicate devices.

Table 5-2. Substantial Equivalence Comparison Table

	Biodesign® Enterocutaneous Fistula Plug (subject device)	**Surgisis® Biodesign® Enterocutaneous Fistula Plug (predicate device)**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated
510(k) number	Unassigned	K082682
Indication	Implantation to reinforce soft tissue for repair of enterocutaneous fistulas	Implantation to reinforce soft tissue for repair of enterocutaneous fistulas

Mode of action	Enterocutaneous fistulas are repaired by sealing the internal opening of the fistula and filling the fistula tract by using cylindrical SIS plugs	Enterocutaneous fistulas are repaired by sealing the internal opening of the fistula and filling the fistula tract by using cylindrical SIS plugs
Components	Implanted Device - Plug - Suture - Molnar Disc - Temporary flange - Expandable gasket	Implanted Device - Plug - Suture - Molnar Disc - Temporary flange
	Delivery System - Pusher - Dilator - Sheath with Captor valve - Transfer tube	Delivery System - Pusher - Dilator - Sheath with Captor valve - Transfer tube
Plug dimensions	Length: 180 mm Diameter: 4 mm	Length: 180 mm Diameter: 4 and 7 mm
Implant materials	- SIS lyophilized, acellular, collagenous, porcine small intestinal mucosa (plug) - Nitinol (flange) - 316 stainless steel (pin and radio-opaque marker) - Polyurethane (flange) - Polydioxanone (PDO) (tether) - Crosslinked SIS (gasket)	- SIS lyophilized, acellular, collagenous, porcine small intestinal mucosa (plug) - Nitinol (flange) - 316 stainless steel (radio-opaque marker) - Polyurethane (flange) - Polydioxanone (PDO) (tether) - Poly (lactic-co-glycolic acid) (PLGA) (pin)
Supplied sterile	Yes	Yes
Sterilization method	Ethylene Oxide	Ethylene Oxide
Intended for single use?	Yes	Yes