March 13, 2018

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

Re: K171817
Trade/Device Name: Biodesign Diaphragmatic Hernia Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWV, FTM
Dated: December 11, 2017
Received: December 13, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K171817

Device Name
Biodesign® Diaphragmatic Hernia Graft

Indications for Use *(Describe)*

The Biodesign® 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 is intended for one time use only.

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

I. SUBMITTER

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906

Phone: (765) 497-3355

Contact Person: Perry W. Guinn
Date Prepared: 12 February 2018

II. DEVICE

Name of Device:	Biodesign® Diaphragmatic Hernia Graft
510(k) Number:	K171817
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh
Regulation number:	21 CFR §878.3300
Product Code:	OWV, FTM
Regulatory Class:	Class II

III. PREDICATE DEVICE

Biodesign® Diaphragmatic Hernia Graft (K133011, Cook Biotech Incorporated)

IV. REFERENCE DEVICE

Meso Bilayer Surgical Mesh (K132025, DSM Biomedical)

V. DEVICE DESCRIPTION

The Biodesign® Diaphragmatic Hernia Graft, the subject device, has the same indications for use and is physically identical to the predicate device (K133011) with the same name. The only difference between the subject device and the predicate device is the rehydration fluid options described in the devices' instructions for use (IFU).

Both the subject and predicate devices are part of a family of implant devices manufactured from porcine small intestine that have been processed to remove the tunica mucosa from the inner intestinal surface and the serosa and tunica muscularis from the outer intestinal surface. After further disinfection to ensure the material is virally inactive, the resulting layer is a three dimensional, acellular, collagen-rich extracellular matrix (ECM) that is termed small intestinal submucosa (SIS). Both the subject and predicate

devices are multilayered SIS sheets configured in two shapes: rectangular shape (7 x 10 cm) and the U-cut shape (7 x 10 cm with U-shaped notch). Both devices are perforated and have polyglycolic acid (PGA) suture stitched across the device and around the perimeter. The purpose of the suture stitching is to prevent delamination due to device handling during implantation. Both devices are provided in a double Tyvek® pouch and are ethylene oxide (EO) sterilized.

Prior to implantation, the Biodesign® Diaphragmatic Hernia Graft, the subject device, can be rehydrated with sterile saline or autologous body fluids (e.g., blood, bone marrow aspirate, or blood concentrates such as platelet concentrate).

Upon implantation, the Biodesign® Diaphragmatic Hernia Graft (both subject and predicate device) will provide mechanical reinforcement of soft tissue in the repair of diaphragmatic/hiatal hernias. Over time, the device will incorporate (remodel) into the body such that no graft material is left behind.

VI. INDICATIONS FOR USE

The Biodesign® 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 is intended for one time use only.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Biodesign® Diaphragmatic Hernia Graft device is identical to its predicate in that they are both intended to reinforce soft tissues where weakness exists including the repair of diaphragmatic/hiatal hernias. Moreover, the subject device's component materials, fundamental scientific technology, and mode of action are identical to that of the predicate device.

The only modification to the Biodesign® Diaphragmatic Hernia Graft (subject device) is the addition of more rehydration fluid options in the instructions for use (IFU). The subject device includes sterile saline and autologous body fluids (e.g., blood, bone marrow aspirate, or blood concentrates such as platelet concentrate) as possible rehydration fluids whereas the predicate device describes rehydration with saline. The reference device Meso Bilayer Surgical Mesh (K132025) also indicated for hiatal hernia repairs, shares the same rehydration fluid information (rehydration with saline or autologous body fluids) as the subject device. Please see **Table 5-1** for a more detailed comparison of the subject, predicate and reference devices.

Table 5-1. Substantial Equivalence Information

Device	Biodesign® Diaphragmatic Hernia Graft (subject device)	Biodesign® Diaphragmatic Hernia Graft (predicate device)	Meso Bilayer Surgical Mesh (reference device)
Manufacturer	CBI	CBI	DSM Biomedical
510 (k) Number	K171817	K133011	K132025
Product Code	Unchanged from predicate device	FTM	FTM, OXH
Intended Use		For implantation to reinforce soft tissues where weakness exists including the repair of diaphragmatic/hiatal hernias	For implantation to reinforce soft tissues where weakness exists in patients requiring soft tissue repair and reinforcement in plastic and reconstructive surgery including but not limited to the following procedures: reinforcement of primary closure such as suture line reinforcement and muscle flap reinforcement; hernia repair (e.g. hiatal, femoral, paracolostomy, umbilical)
Materials and Components		Small intestinal submucosa PGA suture	Porcine tissue and synthetic absorbable polymer
Device Configuration		7x 10 cm size (rectangular and U-cut shape)	Unknown (not specified in 510(k) summary)
Shelf-Life		18 months	36 months
Packaging		foil pouch	Double peel packages
Sterilization		Ethylene Oxide (EO)	Ethylene Oxide (EO)
One-time Use		Yes	Yes
Rehydration Fluid	Saline and autologous body fluids	Saline	Saline and autologous body fluids

PERFORMANCE DATA

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

Non-Clinical testing

Product verification testing was performed on sterilized finished devices to evaluate device mechanical properties after rehydration with body fluids. Comparative tests (rehydration with saline vs. with body fluids) were performed to evaluate the device's

tensile strength, suture retention strength, hydration time and simulated use/handling properties.
Results of the testing showed rehydration with body fluids did not significantly change the mechanical and handling properties of the device.

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® Diaphragmatic Hernia Graft, the subject device, has the same intended use and functions under the same mode of action and fundamental scientific technology as the predicate device with the same name. In addition, the subject device is composed of the same materials and is manufactured using the same processes as the predicate device. The only modification is the addition of autologous body fluids as possible rehydration fluids in the device's IFU. The absence of changes in the fundamental scientific technology and intended use of the device, as well as a review of the risk analysis and completion of verification and validation activities, provide evidence to support the conclusion that the 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.