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 29, 2016

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

Re: K 160869
Trade/Device Name: Biodesign Tissue Graft, Biodesign Dural Graft, Biodesign Peyronie's Repair Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, GXQ
Dated: March 28, 2016
Received: March 30, 2016

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 Parts 801 and 809); 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" (21CFR 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)*
K160869 Page 1 of 3

Device Name
Biodesign Tissue Graft

Indications for Use *(Describe)*
Biodesign Tissue Graft is intended to be used for implantation to reinforce soft tissue

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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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)*
K160869 Page 2 of 3

Device Name
Biodesign Dural Graft

Indications for Use *(Describe)*
Biodesign Dural Graft is intended for use as a dura substitute for the repair of dura mater.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160869 Page 3 of 3

Device Name
Biodesign Peyronie's Repair Graft

Indications for Use *(Describe)*
Biodesign Peyronie's Repair Graft is intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease.

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

Submitted by: Perry Guinn
Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
28 March 2016

This 510(k) is a bundled submission pertaining to three devices manufactured by Cook Biotech Incorporated (CBI):

1. Biodesign Tissue Graft
2. Biodesign Dural Graft
3. Biodesign Peyronie's Repair Graft

This submission is presented as a bundle because the technological modification under consideration is the same for all three devices. Table 5-1 below compiles the main regulatory elements of each subject device, which remain unchanged from their respective predicates.

Table 5-1. Device names, predicates, intended uses and classifications:

Proprietary Name[1]	**Biodesign Tissue Graft**	**Biodesign Dural Graft**	**Biodesign Peyronie's Repair Graft**
Predicate Device	Surgisis (K980431)	Durasis Dural Substitute (K031850)	Surgisis Peyronie's Repair Graft (K062320)
Intended Use	intended to be used for implantation to reinforce soft tissue	intended for use as a dura substitute for the repair of dura mater	intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease
Common/Usual Name	Surgical Mesh	Dura Substitute	Surgical Mesh

[1] The current proprietary names for the devices are Biodesign Tissue Graft, Biodesign Dural Graft and Biodesign Peyronie's Repair Graft. In the past, Surgisis and Durasis Dural Substitute were the proprietary names for the Biodesign Tissue Graft and the Biodesign Dural Graft respectively.

Proprietary Name[1]	**Biodesign Tissue Graft**	**Biodesign Dural Graft**	**Biodesign Peyronie's Repair Graft**
Proposed Classification Name	Mesh, Surgical	Dura Substitute	Mesh, Surgical
Product Code	FTM	GXQ	FTM
Device Class	II	II	II
Regulation Number	878.3300	882.5910	878.3300

Device Descriptions:
The three subject devices of this bundled submission share many of the same technological characteristics:

- Composed of multilayered sheets of processed porcine small intestinal submucosa (SIS).
- Packaged in a Tyvek/PE double pouch.
- Shelf-life of 18 months
- Sterilized using ethylene oxide.

The only differences between the three devices are the indications (and associated labeling) and the dimensional specifications (analogous to the indication and anatomic requirement for each device). Both the indications and the dimensional specifications of each subject device, however, are unchanged from the corresponding predicate device. The indications have been described in Table 5-1 and the dimensional specifications are presented in Table 5-2, below:

Table 5-2. Dimensional Specifications

	Biodesign Tissue Graft	**Biodesign Dural Graft**	**Biodesign Peyronie's Repair Graft**
Product Dimensions (range)	2 cm x 4 cm to 20 cm x 40 cm	2 cm x 2 cm to 10 cm x 20 cm	1 cm x 4 cm to 7cm x 12 cm
Shape	Rectangular	Rectangular	Oval

Description of Technological Modifications:

A technological feature that was present in all three predicate devices was a small hole at the top right corner of the devices, which functioned as a sidedness indicator. Device labeling for predicate devices noted that the functional differences between the sides were

minimal, but cell culture data suggested that the growth of epithelial cells moderately favored one of the sides. Subsequent clinician feedback on the use of the predicate devices confirmed that the functional differences between the sides were minimal and additionally reported that the presence of the sidedness indicator was confusing. Therefore, based on the lack of necessity for a sidedness indicator, all three devices have been modified to no longer include this technologic feature.

Summary of Supporting Evidence for Substantial Equivalence:
The following items are provided to demonstrate substantial equivalence to the predicate devices:

- 510(k) Substantial Equivalence Decision-Making Process as outlined in FDA's Guidance Document, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*
- Review of risk analysis performed in compliance with ISO 14971. Risk analysis methods used include:
    - Failure mode and effects analysis (FMEA)
    - Residual risk review
    - Post production review
- Summary of publications showing SIS performed as expected in versions of the device without the sidedness indicator.

Substantial Equivalence:
Table 5-3 below provides a comparison of the subject devices and their predicates.

Conclusion:
CBI modified three of its devices by removing the sidedness indicator, a small hole at the top right corner of each device. The indicator was initially included in the design of the device based on cell culture data, and not on the functional differences between the sides or reducing specific clinical risk(s). Clinical feedback confirmed functional differences between the sides were minimal and reported that the presence of the sidedness indicator led to confusion. Risk management activities performed in accordance with ISO 14971 on the subject devices did not identify sidedness of the material as a potential risk. Published peer-reviewed literature also confirmed that devices without the sidedness indicator performed as expected, giving evidence of substantial equivalence.

Table 5-3. Substantial Equivalence Information

	Biodesign Tissue Graft Biodesign Dural Graft Biodesign Peyronie's Repair Graft (Subject Devices)	**Surgisis, Durasis Dural Substitute, Surgisis Peyronie's Repair Graft (Predicate Device)**
510(k)	Unassigned	K980431 (Surgisis) K031850 (Durasis) K062320 (Surgisis Peyronie's Repair Graft)
Indication for Use **(**The indications for use of each device in the bundled 510(k) are unchanged from that of each respective predicate device.)	*Biodesign Tissue Graft:* intended to be used for implantation to reinforce soft tissue.	*Surgisis:* intended to be used for implantation to reinforce soft tissue.
	Biodesign Dural Graft: intended for use as a dura substitute for the repair of dura mater.	*Durasis Dural Substitute:* intended for use as a dura substitute for the repair of dura mater.
	Biodesign Peyronie's Repair Graft: intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease.	*Surgisis Peyronie's Repair Graft:* intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease.
Material	Processed Porcine small intestinal submucosa; (constituents of the extracellular matrix)	Processed Porcine small intestinal submucosa; (constituents of the extracellular matrix)
Technological Characteristics	Does not include a sidedness indicator	Includes a sidedness indicator (small hole at the top right corner)
Supplied sterile?	Yes	Yes
Sterilization method	Ethylene Oxide	Ethylene Oxide
Packaging	Double pouched Tyvek/PE	Double pouched Tyvek/PE
Shelf-Life	18 months	18 months
Intended for single use?	Yes	Yes