DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 26, 2016

Cook Biotech, Inc.
Mr. Perry W. Guinn
VP, Regulatory Affairs and Quality Assurance
1425 Innovation Place
West Lafayette, IN 47906

Re: K161221
Trade/Device Name: Biodesign Sling, Biodesign Plastic Surgery Matrix, Biodesign Anal Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: April 27, 2016
Received: April 29, 2016

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" (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,

Jennifer R. Stevenson -A

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)*
K161221, Page 1 of 3

Device Name

Biodesign Sling

Indications for Use *(Describe)*

For implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gasteroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

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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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)*
K161221, Page 2 of 3

Device Name

Biodesign Plastic Surgery Matrix

Indications for Use *(Describe)*

For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.

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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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)*
K161221, Page 3 of 3

Device Name

Biodesign Anal Fistula Plug

Indications for Use *(Describe)*

For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous 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.

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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
27 April 2016

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

1. Biodesign Sling
2. Biodesign Plastic Surgery Matrix
3. Biodesign Anal Fistula Plug

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

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

Proprietary Name	Biodesign Sling	Biodesign Plastic Surgery Matrix	Biodesign Anal Fistula Plug
Predicate Device	Surgisis Sling (K992159)	SIS Plastic Surgery Matrix (K034039)	SIS Fistula Plug (K050337)
Intended Use	Intended to be used for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gasteroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.	Intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.	Intended for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas.

Proprietary Name	Biodesign Sling	Biodesign Plastic Surgery Matrix	Biodesign Anal Fistula Plug
Common/Usual Name	Surgical Mesh	Surgical Mesh	Surgical Mesh
Proposed Classification Name	Mesh, Surgical	Mesh, Surgical	Mesh, Surgical
Product Code	FTM, PAJ, PAG	FTM	FTM
Device Class	II	II	II
Regulation Number	878.3300	878.3300	878.3300

Device Descriptions:

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

- Composed of porcine small intestinal submucosa (SIS)
- Packaged in a Tyvek/PE pouch
- Labeled with a 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 (specific 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 Sling	Biodesign Plastic Surgery Matrix	Biodesign Anal Fistula Plug
Product Dimensions (range) – *as cleared in predicate 510(k)*	20 cm^2 to 140 cm^2 70 to 600 µm thick	2 to 70 mm width up to 200 mm length 100 to 1500 µm thick	2 mm minor diameter to 7 mm major diameter by 100 mm length
Shape	Rectangular	Rectangular	Cone

Description of Technological Modifications:

A series of wash steps was added to the depuration process of the base material for all three subject devices. This process modification serves to further remove impurities from the base material.

In addition, two minor technological changes were made to two of the subject devices:

- Addition of perforations to the Biodesign Sling and Biodesign Plastic Surgery Matrix
- Change in drying method for the Biodesign Sling

The incorporation of the additional wash steps and the minor technological changes do not result in a change to the fundamental technology of the devices.

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

- Analysis of 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)]*
- Biocompatibility analysis performed in accordance with ISO 10993
- Viral Inactivation verification performed in accordance with prEN 12442-3: 2000: Viral inactivation
- Full design control as required by 21CFR 820.30 including review of risk analysis performed in compliance with ISO 14971. Risk analysis methods used include:
    - Failure mode, effects and criticality analysis (FMECA)
    - Residual risk review
    - Post production review
- Mechanical testing for burst force strength and suture retention strength
- Chemical residuals testing
- Measurement of endotoxin levels

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

Conclusion:
CBI modified three of its devices by adding a series of wash steps to the depuration process of SIS. The additional wash steps remove impurities from the base material without affecting the fundamental technology of the devices. Any potential new risks associated with the changes to the predicate devices have been identified by appropriate risk analysis techniques. These potential new risks have been addressed with verification and validation activities that meet the pre-determined acceptance criteria to ensure that no change to device safety has occurred.

Table 5-3. Substantial Equivalence Information

	Biodesign Sling, Biodesign Plastic Surgery Matrix, Biodesign Anal Fistula Plug (Subject Devices)	**Surgisis Sling, SIS Plastic Surgery Matrix, SIS Fistula Plug (Predicate Devices)**
510(k)	K161221	K992159 (Surgisis Sling) K034039 (SIS Plastic Surgery Matrix) K050337 (SIS Fistula Plug)
Indication for Use **(**The indications for use of each device in the bundled 510(k) are unchanged from that of its respective predicate device.)	*Biodesign Sling:* For implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gasteroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.	*Surgisis Sling:* **Same**
	Biodesign Plastic Surgery Matrix: For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.	*SIS Plastic Surgery Matrix:* **Same**
	Biodesign Anal Fistula Plug: For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas.	*SIS Fistula Plug:* **Same**
Material	Porcine small intestinal submucosa; (constituents of the extracellular matrix)	**Same**
Technological Characteristics	Additional wash steps included in base material processing	Original base material processing
Supplied sterile?	Yes	**Same**
Sterilization method	Ethylene Oxide	**Same**
Packaging	Tyvek/PE Pouch	**Same**
Shelf-Life	18 months	**Same**
Intended for single use?	Yes	**Same**