July 13, 2020

Cook Biotech Incorporated
Chris Lotzow
Regulatory Affairs Specialist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K201000
Trade/Device Name: Biodesign Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: April 16, 2020
Received: April 16, 2020

Dear Chris Lotzow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201000

Device Name
Biodesign® Staple Line Reinforcement

Indications for Use *(Describe)*
The Biodesign Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The Staple Line Reinforcement may be used for buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The Staple Line Reinforcement can be used for the reinforcement of the gastric staple line during bariatric surgical procedures, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers.

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

Submission Date: 04/16/2020

K201000

SUBMITTER INFORMATION:

Company Name: Cook Biotech Incorporated

Company Address: 1425 Innovation Place
West Lafayette, IN 47906

Contact Person: Chris Lotzow
Regulatory Affairs Specialist
Phone: 765-497-3355
Fax: 765-807-7709
Email: chris.lotzow@cookbiotech.com

Device Trade Name: Biodesign® Staple Line Reinforcement

Device Common Name: Surgical Mesh

Class: Class II

Classification: 21 CFR 878.3300 – Surgical Mesh

Product Code: FTM

Predicate Devices:

Biodesign® Staple Line Reinforcement (K170945, Cook Biotech Incorporated)

Device Description:

The subject device consists of a thin multi-layer strip of SIS, pre-coated with a ready-to-use contact adhesive that eliminates the need for a separate adhesive (hydrogel), or activation of the adhesive through rehydration to affix the device to surgical stapler jaws. The single-use implant device is provided to the point of use with a protective liner covering the adhesive which has been assembled onto a foam carrier which is suspended in an alignment tray sized for the jaws of a surgical stapler.

The completed device, liner, carrier, and alignment tray unit is then sealed in a foil pouch with an integrated humidity control feature and terminally E-beam sterilized. In order to accommodate a variety of commercially available surgical staplers the device is available in configurations measuring from 0.05mm to 0.6mm in thickness, and in nominal (unfolded) device lengths ranging from 76 mm to 176 mm in length and up to 12 mm wide.

Upon implantation, the Biodesign® Staple Line Reinforcement device will provide mechanical reinforcement of the staple line by buttressing the soft tissue and preventing the surgical staples from tearing through the affected tissue. In addition, the Biodesign® Staple Line Reinforcement device will incorporate (remodel) into the body over time such that no graft material is left behind.

Indications for Use:

The Biodesign® Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The Staple Line Reinforcement may be used for buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The Staple Line Reinforcement can be used for the reinforcement of the gastric staple line during bariatric surgical procedures, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers.

Comparison of Technological Characteristics with the Predicate Device:

The intended use and mode of action of the Biodesign® Staple Line Reinforcement device is the same as the predicate K170945 device in that they are both intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The porcine Small Intestine Submucosa (SIS) material that functionally buttresses the staple line is identical to that of the predicate. Both devices are single use devices which remodel or are absorbed over time. The technological differences between the subject device and the predicate primarily involve the adhesive which is supplied in a ready-to-use formulation that adheres on contact with the surgical stapler. Other changes include design and packaging improvements made possible by this change.

Device Comparison Table

Device	Biodesign® Staple Line Reinforcement (subject device)	Biodesign® Staple Line Reinforcement (predicate device)
Manufacturer	Cook Biotech, Incorporated ****unchanged****	Cook Biotech, Incorporated
510 (k) Number	K201000	K170945
Product Code	FTM ****unchanged****	FTM
Materials/ Components	SIS buttressing strip ****Identical material****	SIS buttressing strip

Device	Biodesign® Staple Line Reinforcement (subject device)	Biodesign® Staple Line Reinforcement (predicate device)
	Pre-coated adhesive (ready-to-use contact adhesive)	Pre-coated adhesive (requires activation with water)
	Center support/carrier (discarded; indirect contact) ****identical material****	Center support (discarded; indirect contact)
	Protective adhesive liner (discarded; indirect contact)	none
	Alignment tray (discarded; non-contact)	Storage tray (discarded; non-contact)
SIS Device Dimensions (unfolded)	Length: up to 176 mm Width: up to 12 mm ****unchanged****	Length: up to 176 mm Width: up to 12 mm
Device Thickness (unfolded)	Overall device thickness: 0.05mm to 0.6mm (depending on layer count)	Overall device thickness: 0.05mm to 0.5mm (depending on layer count)
Shelf-Life	6 months	18 months
Sterile Barrier Packaging	foil pouch	foil pouch
Humidity control packaging	Yes (discarded; non-contact)	No
Sterilization	E-beam process	E-beam process
One-time Use	Yes ****unchanged****	Yes

Performance Data:

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

Biocompatibility testing

Biocompatibility of the predicate device has been established in accordance with the ISO 10993 Biological Evaluation of Medical Devices series of standards. Biocompatibility test data for the subject device has been submitted in support of the substantial equivalence also under the ISO 10993 regime, specifically addressing:

- Part 1: Evaluation and testing within a risk management process
- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- Part 5: Tests for in vitro cytotoxicity
- Part 6: Tests for local effects after implantation
- Part 10: Tests for irritation and delayed-type hypersensitivity
- Part 11: Tests for systemic toxicity

Non-Clinical bench testing

Device performance testing:

Product verification testing was performed on SHS conditioned sterilized finished devices to evaluate the mechanical performance of the subject device for its intended use. Staple line leakage testing confirms that the Biodesign® Staple Line Reinforcement provides adequate staple line buttressing for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers.

Packaging system and shelf life testing:

Non-clinical bench testing was performed on representative SHS conditioned packaging system samples to confirm that the packaging system is adequate to support a 6-month shelf life claim. Testing at additional timepoints is ongoing and the product shelf life will be extended as stability and package system integrity data justifies.

Sterilization

The subject Biodesign® Staple Line Reinforcement device undergoes an E-beam sterilization process, with the sterile barrier established by the primary packaging of each device in a reinforced foil pouch.

Substantial Equivalence:

For purposes of determinations of substantial equivalence under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)), the Biodesign® Staple Line Reinforcement device has the same intended use and functions under the same mode of action as the predicate device. The only change presented to the patient through implantation of the subject device is from the improved adhesive formulation, while other design and packaging changes are exclusively related to ease-of-use prior to loading the device onto the stapler and do not affect the safety or effectiveness of the implanted device. The physical, functional, biocompatibility, and performance characteristics of the subject device are substantially equivalent to the predicate device and do not indicate any new or increased risks to safety or effectiveness when used according to its labelling.

The supplied verification testing therefore supports the determination that the subject Biodesign® Staple Line Reinforcement device is substantially equivalent to the legally marketed predicate K170945 device.

Conclusion:

The Biodesign® Staple Line Reinforcement device is substantially equivalent to the predicate devices K170945 in indications for use, fundamental scientific technology, and technological characteristics. It is as safe and effective as the predicate. Cook Biotech considers the Biodesign® Staple Line Reinforcement device to be substantially equivalent to the predicate device.