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

May 11, 2016

Cook Biotech Incorporated
Ms. Katie Molland
Regulatory Affairs Scientist
1425 Innovation Place
West Lafayette, IN 47906

Re: K161000
Trade/Device Name: Biodesign Otologic Repair Graft
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: KHJ
Dated: April 8, 2016
Received: April 11, 2016

Dear Ms. Molland:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K161000

Device Name
Biodesign Otologic Repair Graft

Indications for Use *(Describe)*
The Cook® Biodesign® Otologic Repair Graft is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures, including but not limited to myringoplasty and tympanoplasty. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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
09 May, 2016

Name of Device:

Trade/Proprietary Names:	Biodesign® Otologic Repair Graft
Common/Usual Names:	Surgical implant polymer material Surgical adjunct polymer
Proposed Classification Name:	Ear, nose, and throat synthetic polymer material
Product Code:	KHJ
Device Class:	21 CFR §874.3620, Class II

Performance Standards: No performance standards that have been established under Section 514 of the Food, Drug and Cosmetic act apply to this device.

Predicate Device:
The predicate device is Biodesign® Otologic Repair Graft (K150594), cleared September 16, 2015.

Intended Use:
The Cook® Biodesign® Otologic Repair Graft is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures, including but not limited to myringoplasty and tympanoplasty.

The device is supplied sterile and is intended for one-time use.

This intended use is identical to that previously cleared under K150594 for the predicate device.

Device Description:
The Cook® Biodesign® Otologic Repair Graft is a porous, absorbable, multi-layer biomaterial composed of laminated extracellular collagen matrix derived from porcine small intestinal submucosa (SIS). SIS is obtained from the intestine using a process that retains the natural composition of matrix molecules such as collagen (Types I, III, VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparin

sulfate), proteoglycans, and fibronectin. The device achieves its intended use by providing a scaffold for cellular invasion and capillary growth, and maintaining a supportive environment for wound management.

The device, other than the packaging, is identical the predicate device (K150594).

Comparison to Predicate Device:
The modification described in this Special 510(k) is a packaging change. The intended use and available device size configurations for the Biodesign Otologic Repair Graft remain identical. The latest proposed presentation of the Biodesign® Otologic Repair Graft (subject device) includes an additional snap-top container packaging element for the circular device sizes. The packaging for the square sheets will not change.

Summary of Non-Clinical Tests:
The following testing was performed to demonstrate substantial equivalence to the predicate device:

- Sterilization adoption
- Package performance testing for accelerated aged devices in the snap-top container packaging
- Cytotoxicity testing of the snap-top tray

Substantial Equivalence:
Table 5-1 below provides a comparison of the subject device and its predicate.

Conclusion:
In summary, the subject device, Biodesign® Otologic Repair Graft, has been compared to the predicate device on the bases of fundamental scientific technology and intended use. Biodesign® Otologic Repair Graft is an FDA-cleared device (K150594). The intended use, material composition, and device design of both subject and predicate devices are identical. The sole difference is the addition of the snap-top tray container to the packaging of the circular devices. Any potential new risks associated with the change in device packaging have been identified by appropriate risk analysis techniques. These potential new risks have been addressed with verification and validation activities in a manner satisfactory to the pre-determined acceptance criteria to ensure that no change to device safety has occurred. Based on the absence of changes in fundamental scientific technology and intended use of the device, as well as on the results of the performed verification and validation testing, it is the position of CBI that the Biodesign® Otologic Repair Graft is substantially equivalent to the predicate device and that the addition of a snap-top tray container for the circular devices does not raise new questions of safety or effectiveness.

Table 5-1. Substantial Equivalence Information

Device	Biodesign® Otologic Repair Graft (Subject Device)	Biodesign® Otologic Repair Graft (Predicate Device)
Manufacturer	Cook Biotech Inc.	Cook Biotech Inc.
510(k) number	K161000	K150594
Intended Use	Unchanged	Biodesign® Otologic Repair Graft is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures, including but not limited to myringoplasty and tympanoplasty.
Product Code		KJH
Material		Porcine small intestinal submucosa; primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)
Dimensions		circular devices (diameter): 4 mm, 6 mm, 9 mm square devices: 2.5 x 2.5 cm 5.0 x 5.0 cm
Supplied sterile?		Yes
Sterilization method		Ethylene Oxide
Intended for single use?		Yes
Packaging configuration	Circular devices: Snap-top tray within Tyvek® Pouch Square devices: Tyvek® Pouch	Tyvek® Pouch