



Food and Drug Administration
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September 16, 2015

Cook Biotech Incorporated
Katie Molland, Ph.D.
Regulatory Affairs Specialist
1425 Innovation Place
West Lafayette, IN 47906

Re: K150594

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: August 14, 2015
Received: August 17, 2015

Dear Dr. 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,

Deborah L. Falls

-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

Indications for Use

510(k) Number (if known)

K150594

Device Name

Biodesign(R) Otologic Repair Graft

Indications for Use (Describe)

The Biodesign Otologic Repair Graft is intended for use as an implant 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

March 4, 2015

Cook Biotech Incorporated

Biodesign® Otologic Repair Graft

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
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Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Biodesign Otologic Repair Graft
Common Name: Surgical implant polymer material/Surgical adjunct polymer material
Classification Regulations: Class II, 21 CFR §874.3620 (KHJ)

INDICATIONS FOR USE:

The Biodesign Otologic Repair Graft is intended for use as an implant 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.

PREDICATE DEVICES: EpiFilm® Otologic Lamina, K982870
MeroGel® Otologic Pack, K001148

DEVICE DESCRIPTION:

The Biodesign Otologic Repair Graft is an absorbable multi-layer biomaterial composed of four layers of laminated extracellular collagen matrix derived from porcine small intestinal submucosa (SIS). The SIS material is lyophilized and then punched into the desired shape. The device is available in 4 mm, 6 mm and 9 mm diameter discs, as well as 2.5 x 2.5 cm and 5 x 5 cm square sheets. Upon implantation, the Biodesign Otologic Repair Graft is infiltrated by the host cells and acts as a scaffold for these cells during the body's natural repair process.

Additionally, the circular configurations of the device are packaged in a dried state and supplied sterile in a tray inside a sealed Tyvek® pouch. The square

configurations of the device are also packaged sterile in a dried state inside a sealed Tyvek[®] pouch.

EQUIVALENCE TO MARKETED DEVICES

The Biodesign Otologic Repair Graft is similar with respect to intended use, materials (naturally occurring constituents of the extracellular matrix) and technological characteristics of the predicate devices in terms of section 510(k) substantial equivalence. Substantial equivalence is supported by biocompatibility testing (conducted in accordance to ISO 10993-1 standards), mechanical, pre-clinical and clinical testing.

Biocompatibility testing

The following biocompatibility tests were performed on sterilized SIS devices which are identical in composition to the Biodesign Otologic Repair Graft (according to the ISO 10993-1 standard):

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- ISO sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

The results of these tests provide evidence that the Biodesign Otologic Repair Graft meets the biocompatibility requirements of the ISO standard.

Mechanical Testing

The Biodesign Otologic Repair Graft material was tested for burst strength and the results compared with its predicates.

The results of this mechanical test provide evidence that the Biodesign Otologic Repair Graft has adequate mechanical strength for its application.

Animal Testing

The SIS material that comprises the Biodesign Otologic Repair Graft was tested in animal studies that included an efficacy study using a chinchilla model and an implant study using a mouse model to characterize cellular response and device degradation. The efficacy study, which compared SIS repair with autologous tissue repair, suggested that SIS was a viable alternative to autologous tissue for tympanic

membrane perforation repair. Additionally, the mouse implant study compared the Biodesign Otologic Repair Graft against the MeroGel Otologic Pack and showed that the subject device performed similarly to the predicate in terms of device degradation, and non-inflammatory host responses. These animal studies provide evidence that the Biodesign Otologic Repair Graft is biocompatible and safe for its application.

Clinical Testing

Prospective data was collected on the use of the SIS material (labeled as Surgisis), the same material that comprises the Biodesign Otologic Repair Graft (D'Eredita, 2012, abstract). In this 404 patient study, the SIS material was used in 217 myringoplasty procedures and compared to 215 temporalis fascia (PTF) repairs performed by the same surgeon. Follow-up was from 2-11 years (average 7.7 years) (data from manuscript submitted by invitation to the International Journal of Pediatric Otorhinolaryngology (February 5, 2013) by D'Eredita). Data analysis included safety, efficacy and procedure duration. No adverse reactions were observed with either type of repair. Stable tympanic membrane closures were seen in 212/217 (97.2%) of SIS repairs compared to 204/215 (94.8%) of PTF procedures. The difference in procedural times between the two (2) arms was not statistically significant.

Additional unpublished data are available in which the device was implanted in:

- a) 18 patients (Hsu, DuPage Medical Group, 2015);
- b) 19 patients (Toh C. *et al.*, Birmingham Heartland Hospital, UK, 2003);
- c) 32 patients (Ofo E. *et al.*, North West London Hospital, UK, 2009); and
- d) 8 patients (Lalwani A. San Francisco, CA, COSM 2003).

No significant adverse events were reported.

Results of these clinical studies show that the Biodesign Otologic Repair Graft is safe and effective for its intended use.

SUBSTANTIAL EQUIVALENCE

Table 1 below provides a comparison of the subject device and its predicates.

Table 1 – Substantial Equivalence Comparison

Device	Biodesign Otologic Repair Graft (subject)	EpiFilm Otologic Lamina (Predicate)	MeroGel™ Otologic Pack (Predicate)
Manufacturer	Cook Biotech Incorporated	Xomed Surgical Products	Medtronic Xomed
510(k) Number	Not assigned	K982870	K001148
Intended Use	The Biodesign Otologic Repair Graft is intended for use as an implant 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.	Intended for use as an implant to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures. EpiFilm Otologic Lamina is indicated for use in myringoplastic and tympanoplastic surgical procedures.	MeroGel Otologic Pack is a space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear and external canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery.
Material	Small intestinal submucosa (SIS) Primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)	HYAFF® (ester of hyaluronic acid, a naturally occurring constituent of the extracellular matrix.)	HYAFF® (ester of hyaluronic acid, a naturally occurring constituent of the extracellular matrix.)
Method of action	Has a scaffold structure which is infiltrated with host cells, forms gel as the process of remodeling occurs	Has micro-perforation providing permeable surface and acts as a scaffold for migrating host cells	Hygroscopic, forms gelatinous mass in contact with fluids
Dimensions	4 mm, 6mm, 9 mm diameter 2.5 x 2.5 cm 5 x 5 cm	8 mm diameter (EpiDisc)* 2.5 cm x 2.5 cm	1 cm x 5 cm, 4 cm x 4 cm
Thickness	100 µm to 500 µm	NA	340 µm†
Sterilization	Ethylene oxide	Gamma irradiation	Gamma irradiation
Shelf life	18 months	NA	48 months

NA – Not available

†N=2

*EpiDisc and EpiFilm Otologic Lamina are the same material and sold under the same 510(k). EpiDisc is a smaller sized device than EpiFilm

CONCLUSION: The biocompatibility, pre-clinical and clinical tests performed on the Biodesign Otologic Repair Graft show that the device is substantially equivalent to its predicates.