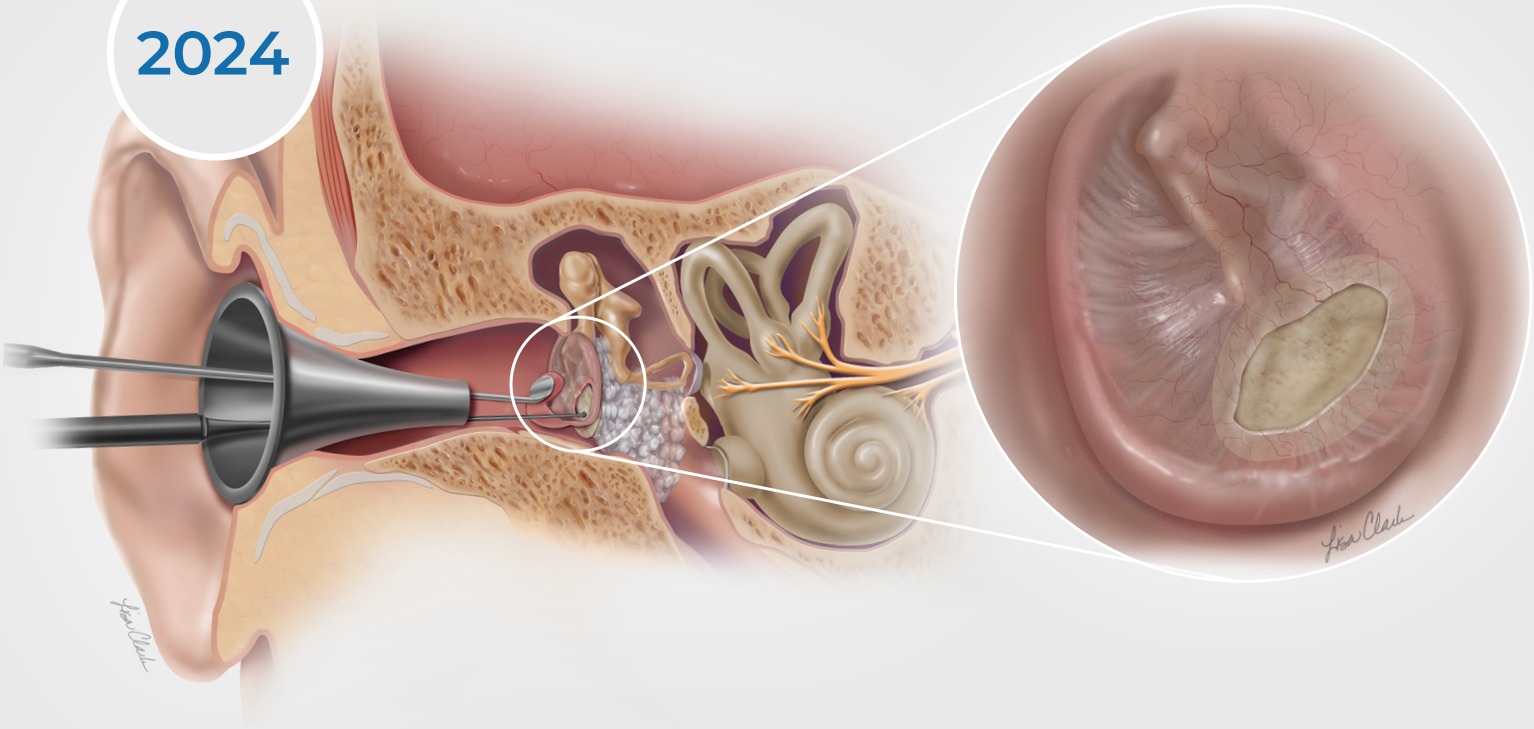
Biodesign®

OTOLOGIC REPAIR GRAFT

Value Analysis*

AND PRODUCT INFORMATION PACKET

2024



C2Dx®

Harvest results, not patient tissue[1-3]

Reliable closure, excellent handling, and time saving[1]

*Prepared in the context for value analysis committees in a hospital setting

Disclaimer: The information provided herein reflects C2Dx's analysis of the procedure(s) and/or device(s), based upon the instructions for use (IFU), from sources that may include, but are not limited to, published journal articles, data on file with the manufacturer, physician and consultant input, the CPT coding system, and Medicare payment systems. This analysis is provided for general information purposes only, and C2Dx does not warrant or assume any liability or legal responsibility for this information. The entity assessing the product is solely responsible for determining the accurate cost of treatment at its site and the codes assigned to the services and items in the medical record. Each entity should use its own economic data to fully assess the assumptions and analysis stated herein.

Contents

Product overview

The 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 graft enables a truly minimally invasive approach to ear surgery with no donor site required and thus, no additional scar for the patient.[1]

Key product features:

Reliable closure:	Biodesign material remodels into natural host tissue with an overall success rate of 91% across published literature[1-9] and no statistically significant difference in audiometric results when compared to temporalis fascia.[1,10]
Excellent handling:	Biodesign material is easy to manipulate, allowing for improved surgical precision during graft placement.[1]
Time saving:	The Biodesign Otologic Repair Graft reduces the need to harvest autologous tissue, significantly decreasing intraoperative time.[1]

Otologic repair grafts are designed to provide value for:

Patients:	Reduces the need to harvest autologous tissue, helping avoid additional scarring and comorbidities.[1,3]
Healthcare providers:	Remodels into natural host tissue with an overall success rate of 91% across published literature;[1–9] easy to manipulate, allowing for improved surgical precision[1] and can be placed using either an endoscopic or microscopic technique[2,14]
Hospitals:	Reduces the need to harvest autologous tissue, decreasing intraoperative time by an average of 7.7 minutes[1] per procedure, potentially saving costs when compared to temporalis fascia.
Payers:	Potential cost savings by reducing the need to harvest patient tissue, potentially avoiding additional comorbidities[1,3,13]

The key considerations for your value analysis include the following:

1. The product:

- The Biodesign Otologic Repair Graft, with its convenient sizes, manipulability, and straightforward positioning, allows for increased surgical precision,[1] potentially reducing the intraoperative portion of the procedure time by 7.7 minutes when compared to autologous tissue harvest.[1]

2. The financial impact:

- The Biodesign Otologic Repair Grafts are a potential cost-effective option for tympanic perforations, since they eliminate the need for harvesting patient tissue, which means it may be less costly to treat patients.[1,3,13]

NOTE: References may be found on pages 26-27 of this packet.

Product information

Product design

The Biodesign Otologic Repair Graft is a natural extracellular matrix (ECM) derived from porcine small intestinal submucosa (SIS). The ECM is a complex latticework of proteins and structural molecules that acts as a scaffold for cells.[11] The Cook's proprietary processing methodology decellularizes the SIS material while preserving natural matrix molecules such as collagen, proteoglycans, and glycosaminoglycans.[12] The otologic repair graft comes in five sizes and two shapes ranging from a circle 0.4 cm in diameter to a square measuring 5 x 5 cm.

Deployment method

Prepare the wound bed using standard surgical techniques and control bleeding prior to applying the graft. Choose the appropriately sized graft based on defect size, ensuring that the graft covers the entire defect. The graft may be placed in a dry state, but if hydrated, hydrate the graft for no longer than 1 minute. Complete the standard surgical procedure and secure the graft with preferred method of fixation (e.g., otologic packing or other appropriate method). For additional instructions on preparation, device selection, and postoperative care; please reference the Instructions for Use.

Product intended use

The 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.

NOTE: References may be found on pages 26-27 of this packet.

Value analysis

Overview

Using cost, quality, and clinical outcomes to make evidence-based decisions

Healthcare professionals understand the importance of a high-quality product and one that makes economic sense as well. In this ever-changing healthcare landscape, healthcare providers must not only focus on the best clinical option for their patients, but also the most cost-effective option. They can no longer focus solely on the individual procedure, but must consider the total care of that patient, including follow-up, return to work, and overall quality of life.

The value analysis for the Biodesign Otologic Repair Graft focuses on the variables that can be controlled: repair approach and graft choice. Thus, healthcare providers can make evidence-based decisions to treat their patients.

Use of the Biodesign Otologic Repair Graft potentially benefits multiple entities, including the following:

Patients:

Reduces the need to harvest autologous tissue, helping avoid additional scarring and comorbidities[1,3]

Healthcare providers:

Remodels into natural host tissue with an overall success rate of 91% across published literature;[1–9] easy to manipulate, allowing for improved surgical precision[1] and can be placed using either an endoscopic or microscopic technique[2,14]

Hospitals:

Reduces the need to harvest autologous tissue, decreasing intraoperative time by an average of 7.7 minutes[1] per procedure, potentially saving costs when compared to temporalis fascia

Payers:

Potential cost savings by reducing the need to harvest patient tissue, potentially avoiding additional comorbidities[1,3,13]

NOTE: References may be found on pages 26-27 of this packet.

Economic value analysis

Economic value and device selection for otologic repair procedures

The alternative to an otologic graft is harvesting fascia from behind the ear. The harvested fascia (which leaves a scar after complete healing), is then placed in the ear. In addition, revision tympanoplasty and/or second-look procedures are common practice in pediatric otology. Previous temporalis fascia harvest may not leave sufficient tissue for a second graft at revision surgery, in second-look cases, or when autogenous temporalis fascia quality is poor.[1] Use of the otologic graft during primary surgery reduces the need to harvest patient tissue and leaves the temporalis fascia as an option if needed in the future. Overall cost of care must be considered as part of the value analysis when assessing options for tympanoplasty or myringoplasty repair.

The potential need for a revision surgery, and an extended recovery time due to donor site healing, may increase the overall cost to treat the patients.

- The weighted average cost of a hospital outpatient otologic graft surgery without complications is approximately **$5,552.82**[a]
- Otologic graft surgeries are reimbursed on average $5,196.50[b] by Medicare in the hospital outpatient setting. Thus, the total reimbursement is less than the average hospital outpatient procedure cost.

Assume your hospital performs 20 tympanic membrane repair procedures per year.

	Biodesign Otologic Repair Graft	Temporalis fascia
Closure rate	91%[1–9]	83%[15,16]
Estimated number of successful closures per year	18	16
Estimated weighted average per procedure cost (includes graft cost)	$5,194.15[c,13,21]	$5,552.82
Estimated average annual cost (includes procedure cost + graft or temporalis fascia surgery cost)	$103,882.93	$111,056.33
Estimated annual savings by using Biodesign Otologic Repair Graft instead of temporalis fascia	$7,173.40	
Failed initial procedures (either the Biodesign Otologic Repair Graft or temporalis fascia) plus secondary crossover procedure annual costs[d]	$113,878.00	$128,716.43
Estimated annual savings by using Biodesign Otologic Repair Graft for the initial procedure (91% versus 83% closure rate)	$14,838.43	
With better closure rates and decreased procedural time, you could potentially eliminate 2 secondary procedures and save an estimated $7,200 to $15,000 annually.		

NOTE: By potentially eliminating secondary procedures and reducing OR time during the initial graft placement, you may free up additional time to perform other procedures.

For more information on this economic value analysis and to further understand the use of the Biodesign Otologic Repair Graft, please contact your local C2Dx representative.

a The procedure cost is the average weighted geometric mean cost of CPT codes 69620, 69631, 69632, 69633, 69635, 69636, 69637, 69641, 69642, 69643, 69644, 69645, and 69646 from the CY2023 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. Centers for Medicare & Medicaid Services Web site. https://www.cms.gov/medicaremedicare-fee-service-paymenthospitalout patientppshospital-outpatient-regulations-and-notices/cms-1772-fc. Accessed November 28, 2022).

b The weighted average Medicare reimbursement rate was calculated utilizing CPT codes 69620, 69631, 69632, 69633, 69635, 69636, 69637, 69641, 69642, 69643, 69644, 69645, and 69646

c The estimated average cost is calculated using the most popular Biodesign Otologic Repair Graft at $268, based on 20 procedures per year per site and the hospital outpatient weighted cost of $5,552.82, less 7.7 minutes of operating room time at $41 per minute ($315.70),[15] less APC device related costs ($310.97).

d Crossover: Those failed Biodesign Otologic Repair Graft procedures (2 out of 20) would be repaired by temporalis fascia and those failed temporalis fascia procedures (4 out of 20) would be repaired by Biodesign Otologic Repair Grafts.

NOTE: References may be found on pages 26-27 of this packet.

Biodesign Otologic Repair Graft technology

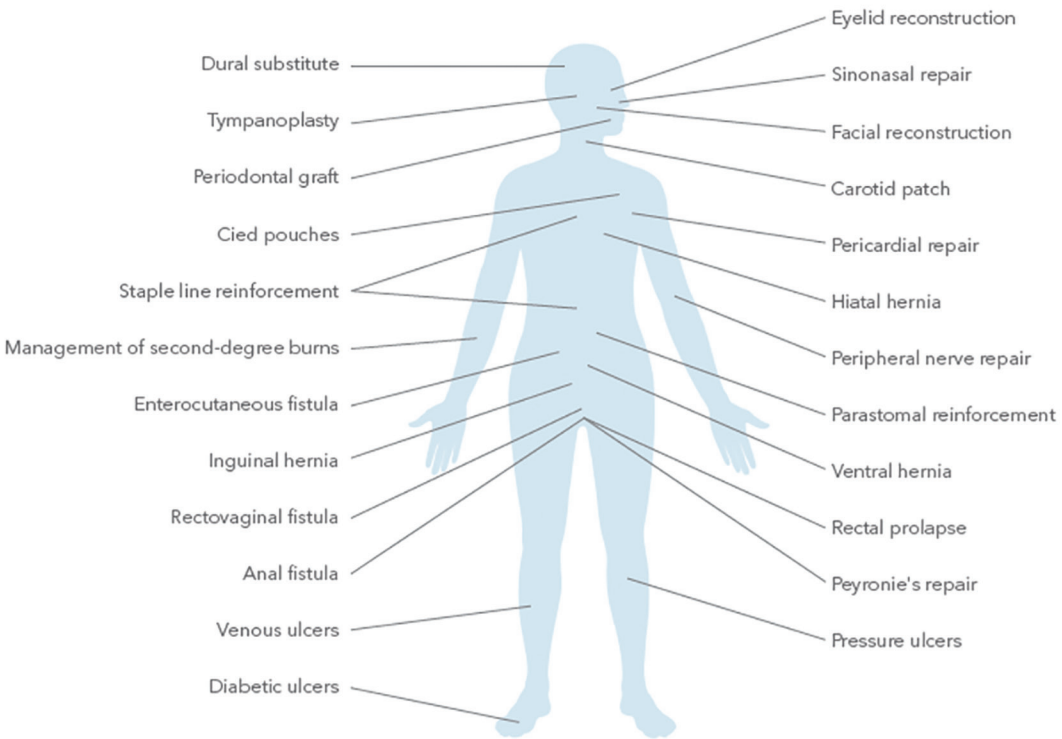
What is SIS?

- SIS is a platform technology behind numerous tissue-repair products that span multiple medical specialties.
- SIS is derived from porcine small intestinal submucosa, a naturally occurring ECM located between the mucosal and muscular layers of the small intestine.
- The ECM is a complex latticework of proteins and structural molecules that acts as a scaffold for cells.[11]
- The proprietary processing methodology decellularizes the SIS material while preserving natural matrix molecules such as collagen, proteoglycans, and glycosaminoglycans.[12]
- The result is a scaffold that, when implanted, provides a location for host cells to infiltrate and remodel into vascularized tissue.[22]

How does SIS work?

- There are three essential components to healing: a scaffold, signals, and cells.
- The SIS's open lattice structure provides a scaffold for tissue ingrowth.[22]
- The body's signaling mechanisms help patient cells infiltrate the scaffold and remodel into natural host tissue.[1–3]

SIS has been used in numerous applications throughout the body:



NOTE: References may be found on pages 26-27 of this packet.

Summary

Surgical closure of a tympanic membrane perforation involves the use of a graft or other material, commonly temporalis fascia. Treating tympanic membrane perforations can be complicated, but choosing a repair type does not have to be complicated. The Biodesign Otologic Repair Graft aids in the natural healing process, while offering a minimally invasive approach to ear surgery with no donor site required, and thus, no additional scarring.[1] The data referenced throughout this document can help healthcare providers make evidence-based decisions. By using the information included, providers can determine when the Biodesign Otologic Repair Graft is ideal for their patients.

The Biodesign Otologic Repair Grafts are designed to provide value for:

Patients:	Reduces the need to harvest autologous tissue, helping avoid additional scarring and comorbidities.[1,3]
Healthcare providers:	Remodels into natural host tissue with an overall success rate of 91% across published literature[1–9] easy to manipulate, allowing for improved surgical precision[1] and can be placed using either an endoscopic or microscopic technique[2,14]
Hospitals:	Reduces the need to harvest autologous tissue, decreasing intraoperative time by an average of 7.7 minutes per procedure, potentially saving costs when compared to temporalis fascia[1]
Payers:	Potential cost savings by reducing the need to harvest patient tissue, potentially avoiding additional comorbidities[1,3,13]

The key considerations for your value analysis include:

1. **The product:**

   The Biodesign Otologic Repair Graft with its convenient sizes, manipulability, and straightforward positioning allows for increased surgical precision,[1] potentially reducing the intraoperative portion of the procedure time by 7.7 minutes[1] when compared to autologous tissue harvest.

2. **Specialties impacted:** Otolaryngology/ENT

3. **The financial impact:**

   The Biodesign Otologic Repair Grafts are a potential cost-effective option for tympanic perforations, since they eliminate the need for harvesting patient tissue, which means it may be less costly to treat patients.[1,3,13]

4. **Impact on patients:**

   With an elimination in the need to harvest patient tissue, patients endure less scarring and a shorter procedure, likely increasing the cosmetic satisfaction of the repair.[1-3]

NOTE: References may be found on pages 26-27 of this packet.

Materials management information

Order numbers and sizing

Order Number	Reference Part Number	Size (cm)
Biodesign Otologic Repair Graft		
G44451	ENT-OTO-2.5X2.5	2.5 X 2.5
G44452	ENT-OTO-5X5	5.0 X 5.0
G44840	ENT-OTO-0.4-0.6	0.4 & 0.6 (diameter)
G44839	ENT-OTO-0.6-0.9	0.6 & 0.9 (diameter)

Product specifications

The 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.

Material composition

The Biodesign Otologic Repair Graft is composed of porcine SIS. SIS is an acellular, collagen-rich material derived from porcine small intestine, which has been used to reinforce soft tissues for over 20 years. SIS is manufactured by first removing the tunica mucosa from the inner intestinal surface and the serosa and tunica muscularis from the outer surface of the porcine small intestine. Further processing removes cells and nuclear matter from the material, leaving behind a three-dimensional, decellularized, collagen-rich extracellular matrix (ECM) that is not chemically cross-linked.

SIS devices are unique in that they not only act as a scaffold wherein cells can infiltrate and grow into the defect where SIS is implanted, but they are processed to retain a rich array of matrix molecules such as collagen (Types I, III, IV, and VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparin sulfate), proteoglycans, and fibronectin.[12,17,18] After implantation, the SIS material is infiltrated by host cells while being slowly resorbed into the body, metabolized, and excreted from the body via urine.[19] Simultaneously, normal cell-mediated biological turnover processes replace the SIS with host soft tissue.[14,20] The overall process of SIS integration in vivo is termed “remodeling.”

NOTE: References may be found on pages 26-27 of this packet.

Material composition (continued)

The Biodesign Otologic Repair Graft is decellularized, lyophilized (i.e., freeze-dried) porcine SIS with a nominal thickness measuring 0.25 mm. Due to the biologic nature of the source material, the device may vary minimally in thickness, ranging from 0.17 mm to 0.45 mm.[e] The Biodesign Otologic Repair Graft is available in five sizes and two shapes. Specifically, the device is offered in three pre-shaped discs (0.4, 0.6, and 0.9 cm diameters) or in two square sheets (2.5 x 2.5 cm and 5 x 5 cm) designed to be easily trimmed to the desired graft size and shape based on the specific patient need.

For user convenience, the circular configurations are marketed in pairs of varying diameters (0.4 and 0.6 cm or 0.6 and 0.9 cm). The devices are packaged in a red polypropylene tray that has two differently sized ethylene oxide-permeable cavities. The tray is then packaged and sealed in a Tyvek® pouch. This paired arrangement allows the physician to choose the most appropriate graft size at the time of the procedure, since it may not always be possible to accurately determine the graft size needed prior to the preparation of the surgical site. Notably, once the appropriately sized graft is implanted, the Instructions for Use direct the physician to discard all open and unused portions of the device.

Coding and reimbursement

For the most up-to-date information, please visit c2dx.com

Additional resources

- Certificate of Conformance
- Religious Concerns Memo
- Latex-Free Letter
- Product Datasheet
- Clinical Data Summary
- Biodesign Otologic Repair Graft Brochure
- Biodesign Advanced Tissue Repair Brochure

e. Represents ranges from 5% to 95% percentile. Data on file at RTI D00253289.

NOTE: References may be found on pages 26-27 of this packet.

FDA 510(k) clearance letter

(This document is also available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K150594.)

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

September 16, 2015

Cook Biotech Incorprated
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

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)*
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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

March 4, 2015

Cook Biotech Incorporated

Biodesign® Otologic Repair Graft

Manufacturer Name:	Cook Biotech Incorporated 1425 Innovation Place West Lafayette, Indiana 47906 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.

5-5

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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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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

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

Instructions for use (IFU)

NOTE: For the most up-to-date IFU, please reference Instructions for Use.

BIODESIGN OTOLOGIC REPAIR GRAFT

DEVICE DESCRIPTION

The Biodesign Otologic Repair Graft is a porous 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.[1,2,3]

INTENDED USE

The 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.

CONTRAINDICATIONS

This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

GENERAL

Users should be familiar with surgical technique for various otologic procedures, including but not limited to myringoplasty and tympanoplasty

PRECAUTIONS

- This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- Do not resterilize. Discard all open and unused portions of the device.
- The device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Avoid packing external canal with adherent dressings or applying excessive pressure in the ear canal.
- Please take care when opening tray packaging to ensure that device remains seated in the tray.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical device materials in otologic procedures:

- Abscess formation
- Allergic reaction
- Calcification
- Cholesteatoma
- Excessive redness, pain, swelling, or blistering
- Fever
- Infection
- Inflammation (initial application of surgical device materials may be associated with transient, mild, localized inflammation)
- Mastoiditis
- Migration
- Persistence of perforation
- Recurrence
- Retraction pockets
- Seroma
- Squamous cysts
- Thickening of the tympanic membrane

STORAGE

This device should be stored in a clean, dry location at room temperature.

STERILIZATION

This device has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Sterile scissors
- **Hydration fluid:** sterile room temperature saline or sterile lactated Ringer's solution

NOTE: Always handle the device using aseptic technique. Minimize contact with latex gloves.

PREPARATION

1. Prepare the wound bed using standard surgical techniques. Ensure the area is free of exudate and devitalized tissue. An initial excision or debridement of the site may be necessary to ensure the wound edges contain viable tissue.
2. Control bleeding prior to applying the Biodesign® Otologic Repair Graft.

SELECTION

3. Choose the appropriately sized device based on defect size, ensuring that the device covers the entire defect surface area and extends slightly beyond the wound margins.
4. Aseptically remove the device from the packaging.
5. Cut the device as needed with sterile scissors to cover the defect.

APPLICATION

6. The device may be placed in a dry state. Alternatively, if device hydration prior to application is preferred, hydrate the device in hydration fluid for no longer than 1 minute.
7. Verify that the device extends beyond the margins of the defect to obtain the appropriate overlap. Reposition the device as necessary.
8. Following placement, ensure the device is adequately hydrated.
9. Complete the standard surgical procedure and secure the device with preferred method of fixation (e.g. otologic packing or other appropriate method).
10. Discard any unused portions of the device according to institutional guidelines for medical waste.

POSTOPERATIVE CARE

- To provide the best environment for tissue integration, provide the patient with a list of standard post-procedure recommendations. The following should be considered:
- Avoid exposing surgical site to direct moisture for 3 weeks unless approved by physician.
- Avoid exposing surgical site to rapid changes in pressure for 2 to 3 weeks unless approved by physician.

ASSESSMENT

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of Biodesign may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

11. As healing occurs, sections of Biodesign may gradually peel. Carefully remove any remaining loose product around the edge as needed.
12. Gently cleanse the wound surface with sterile saline; leave the ECM gel intact.
13. Carefully reassess the wound and record healing progression and other relevant information.

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