DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 7, 2016

Kensey Nash Corporation Dba DSM Biomedical
Brianna Schehr
Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19431

Re: K160474
Trade/Device Name: DSM Biomedical Porcine Pericardium Dental Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: May 19, 2016
Received: May 19, 2016

Dear Ms. Brianna Schehr:

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,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

K160474

Device Name

DSM Biomedical Porcine Pericardium Dental Membrane

Indications for Use *(Describe)*

DSM Biomedical Porcine Pericardium Dental Membrane is indicated for:
- simultaneous use of GBR-membrane and implants
- augmentation around implants placed in immediate extraction sockets
- augmentation around implants placed in delayed extraction sockets
- localized ridge augmentation for later implantation
- alveolar ridge reconstruction for prosthetic treatment
- filling of bone defects after root resection, cystectomy, removal of retained teeth
- guided bone regeneration in dehiscence defects
- guided tissue regeneration procedures in periodontal defects

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: DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Brianna Schehr
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(P) 484-713-2100
(F) 484-713-2806

Date Prepared: June 5, 2016

Device:

Trade Name:	**DSM Biomedical Porcine Pericardium Dental Membrane**
Common/Usual Name:	Porcine Derived Collagen Dental Membrane
Regulation Number:	21 CFR 872.3930
Regulation Name:	Bone Grafting Material
Regulatory Class:	II
Product Code:	NPL (Barrier, Animal Source, Intraoral)
Advisory Panel:	Dental

Predicate Device: Bio-Gide® (K042197) [Geistlich-Pharma]

Device Description:

The DSM Biomedical Porcine Pericardium Dental Membrane is a resorbable porcine pericardium derived extracellular matrix barrier membrane for guided tissue and bone regeneration in dental applications. The device is manufactured using a standardized, controlled, multistage process. The origin of all animals is the United States of America. It is provided as a lyophilized sheet in sizes 15 mm x 25 mm, 20 mm x 30 mm, and 30 mm x 40 mm, which may be hydrated with saline or blood. It can be easily trimmed or shaped to the appropriate size to fit the defect to be treated. When hydrated, the membrane is easily drapeable while maintaining suture tear resistance. It is supplied sterile by ethylene oxide and is for single use only.

The DSM Biomedical Porcine Pericardium Dental Membrane functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled, resorbed, and replaced by host tissue. Animal studies have shown that DSM Biomedical Porcine Pericardium Dental Membrane is resorbed within 2 to 9 weeks.

Indications For Use:

DSM Biomedical Porcine Pericardium Dental Membrane is indicated for:

- simultaneous use of GBR-membrane and implants;
- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects;
- guided tissue regeneration procedures in periodontal defects.

Basis for Substantial Equivalence:

The DSM Biomedical Porcine Pericardium Dental Membrane is substantially equivalent in terms of indications for use, material composition, technological characteristics, and performance characteristics to the predicate device, Bio-Gide® [Geistlich-Pharma] K042197.

A comparison of DSM Biomedical Porcine Pericardium Dental Membrane and the predicate device supports substantial equivalence based on the design, material, indications for use, technical characteristics, and performance. The technological characteristics of the DSM Biomedical Porcine Pericardium Dental Membrane are equivalent to the predicate device as shown in extensive material and physical characterization testing. The subject and predicate devices are derived from the same animal source, are provided sterile and for single use. Both devices are provided in lyophilized form in multiple size offerings. The micro-architecture is comparable as both contain a matrix of similarly sized

pores. The suture strength is also comparable, as both have suture tear resistance strength to withstand the forces of suturing to maintain positioning during implantation.

The performance of the DSM Biomedical Porcine Pericardium Dental Membrane was evaluated in a canine intrabony defect model compared to the predicate device. The study showed that coverage of dental bone defects with the subject device or predicate device results in similar new bone formation based on histopathology evaluations. The subject device degraded faster than the predicate, but based on clinical observation and extent of bone regeneration, this faster degradation does not present questions of equivalence.

Characteristic	**DSM Biomedical Porcine Pericardium Dental Membrane** ***(Subject Device)***	**Bio-Gide®** ***(K042197: Predicate Device)***
Indications for Use	DSM Biomedical Dental Bone Graft is indicated for simultaneous use of GBR-membrane and implants; augmentation around implants placed in immediate extraction sockets; augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects; guided tissue regeneration procedures in periodontal defects.	Bio-Gide® is indicated for simultaneous use of GBR-membrane and implants; augmentation around implants placed in immediate extraction sockets; augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects; guided tissue regeneration procedures in periodontal defects.
Target Population	Human, oral, periodontal	Human, oral, periodontal
Animal Origin	Porcine	Porcine

Characteristic	DSM Biomedical Porcine Pericardium Dental Membrane *(Subject Device)*	Bio-Gide® *(K042197: Predicate Device)*
Material Composition	Porcine Pericardium-derived extracellular matrix	Purified porcine collagen
Form	Resorbable lyophilized membrane	Resorbable lyophilized membrane
Sizes	15 mm x 25 mm, 20 mm x 30 mm, 30 mm x 40 mm	13 mm x 25 mm, 25 mm x 25 mm, 40 mm x 50 mm
Operating Principles	Cell-Occlusive Implantable Resorbable Biocompatible	Cell-Occlusive Implantable Resorbable Biocompatible
Reusable	Single use only	Single use only
Packaging	Double pouch	Double blister
Non-Pyrogenic	Yes	Yes
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}
Sterilization Method	Ethylene Oxide	Gamma Irradiation
Shelf Life	6 months	36 months

Performance Data:

The substantial equivalence of DSM Biomedical Porcine Pericardium Dental Membrane and its predicate was demonstrated based on *in vitro* characterization studies, biocompatibility studies, *in vivo* animal studies, and clinical history of the predicate device.

FDA recognized standard ISO 22803 *Dentistry—Membrane Materials for Guided Tissue Regeneration in Oral and Maxillofacial Surgery—Contents of a Technical File*, was used to guide the characterization of

the DSM Biomedical porcine Pericardium Dental Membrane as no applicable performance standards exist for this device.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate device. A series of device characterization and bench tests were conducted which included an evaluation of physical properties such as dimensional analysis, micro-architecture analysis including percent porosity and median pore diameter, and resorption. Evaluation of resorption was performed in a canine intrabony defect model. Material characterization testing of the DSM Biomedical Porcine Pericardium Dental Membrane was completed to evaluate the material properties of the device. Bench testing was completed to verify that the device exhibits drapeability when hydrated, adheres to tissue, and maintains sufficient suture tear resistance strength.

In addition to the *in vitro* characterization tests, a canine intrabony defect animal study was performed to evaluate membrane degradation and new bone formation following treatment with the DSM Biomedical Porcine Pericardium Dental Membrane compared to the predicate device.

Biocompatibility testing was completed in accordance with the requirements of *ISO 10993-1: 2009, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process* for a permanent implant device with tissue/bone contact. Testing included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Genotoxicity, Hemocompatibility, Subacute Systemic Toxicity, Chronic Systemic Toxicity, and Implantation. Other testing included a viral inactivation study and residual chemical assessment. Results indicate that the device's biocompatibility profile is acceptable.

Biological Effect	Standard	Test	Result
Cytotoxicity	ISO 10993-5	L929 Neutral Red Uptake	Pass
Sensitization	ISO 10993-10	Kligman Maximization Test	Pass
Irritation	ISO 10993-10	Intracutaneous Injection	Pass
Acute Systemic Toxicity	ISO 10993-11	Systemic Injection Test	Pass
		Rabbit Pyrogen Test	Pass
Hemocompatibility	ISO 10993-4	Hemolysis—Rabbit Blood—Indirect Contact	Pass
Subacute Systemic Toxicity, Implantation	ISO 10993-6 ISO 10993-11	28-Day Systemic Toxicity in Rats via Intramuscular and Subcutaneous Implantation	Pass

Chronic Systemic Toxicity and Implantation	ISO 10993-6 ISO 190993-11	26-Week Systemic Toxicity in Rats via Subcutaneous Implantation	Pass
Genotoxicity	ISO 10993-3	*S. Typhimurium* and *E.Coli* Reverse Mutation Assay	Pass
		Chromosomal Aberration	Pass
		Rodent Blood Micronucleus Assay	Pass

Given the similarities between the DSM Biomedical Porcine Pericardium Dental Membrane and the predicate device, it was determined that clinical data was not necessary to demonstrate substantial equivalence.

Conclusion:

Pursuant to section 510(k), DSM Biomedical Porcine Pericardium Dental Membrane is substantially equivalent to the predicate device Bio-Gide® with regard to indication for use, material, technological characteristics, including principles of operation, and performance characteristics as shown in an anatomically relevant animal model.