



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 16, 2017

Kensey Nash Corporation DbA DSM Biomedical
Susan Pileggi
Senior Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K170245

Trade/Device Name: DSM Biomedical Dental Bone Graft
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: April 12, 2017
Received: April 13, 2017

Dear Susan Pileggi:

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,


Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170245

Device Name

DSM Biomedical Dental Bone Graft

Indications for Use (Describe)

DSM Biomedical Dental Bone Graft is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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
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Exton, PA 19341

Contact Person: Susan Pileggi
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Date Prepared: April 11, 2017

Device:

Trade Name:	DSM Biomedical Dental Bone Graft
Common/Usual Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material
Classification Regulation:	21 CFR 872.3930
Device Class:	II
Device Code:	NPM
Advisory Panel:	Dental

Predicate Device: Bio-OSS® (K033815) [Geistlich-Pharma]

Device Description

The DSM Biomedical Dental Bone Graft is a non-pyrogenic porous bone mineral matrix for use in periodontal, oral, and maxillofacial surgery. It is produced by removing organic components from porcine bone. The composition of DSM Biomedical Dental Bone Graft meets the requirements of *ASTM F 1581 Standard Specification for Composition of Anorganic Bone for Surgical Implants*. The device is provided as cancellous granules approximately 0.25 - 1.0mm in size. It is supplied sterile by gamma irradiation and is for single use only.



Indications For Use:

DSM Biomedical Dental Bone Graft is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Basis for Substantial Equivalence

The DSM Biomedical Dental Bone Graft is substantially equivalent in terms of indications for use, material composition, technological characteristics and performance characteristics to the predicate device, Bio-OSS® [Geistlich-Pharma] K033815.

DSM Biomedical Dental Bone Graft and the predicate device have identical indications for use. Both are for use in the same target population. They are similar in sizes offered with the subject device sizes falling within the range of the predicate sizes. Both are sterilized by gamma irradiation and supplied in a single use vial. The materials are shown to be an osteoconductive hydroxyapatite bone mineral to aid in bone formation. The devices are both trabecular and contain interconnecting macro and micro pores. The devices are both biocompatible. The subject device is derived from porcine bone while the predicate is derived from bovine bone. This does not raise questions of substantial equivalence as both types of bone are subjected to manufacturing processes which remove organic content from the source bone. Chemical and physical characteristics have been shown to be substantially equivalent in benchtop and animal testing.



Characteristic	DSM Biomedical Dental Bone Graft <i>(Subject Device)</i>	Bio-OSS® <i>(K033815: Predicate Device)</i>
Indications for Use	DSM Biomedical Dental Bone Graft is indicated for augmentation or reconstructive treatment of the alveolar ridge; filling of infrabony periodontal defects; filling of defects after root resection, apicoectomy, and cystectomy; filling of extraction sockets to enhance preservation of the alveolar ridge; elevation of the maxillary sinus floor; filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).	Bio-OSS® is indicated for augmentation or reconstructive treatment of the alveolar ridge; filling of infrabony periodontal defects; filling of defects after root resection, apicoectomy, and cystectomy; filling of extraction sockets to enhance preservation of the alveolar ridge; elevation of the maxillary sinus floor; filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).
Target Population	Human, oral, periodontal	Human, oral, periodontal
Source Bone	Porcine bone	Bovine bone
Form	0.25 - 1.0mm granules	0.25mm - 1.0mm or 1.00mm - 2.0mm granules
Supplied As	Granules supplied in a single use sterilized vial	Granules supplied in a single use sterilized vial
Material	Porcine-derived osteoconductive hydroxyapatite bone mineral	Bovine-derived osteoconductive hydroxyapatite bone mineral
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Performance	Bone formation	Bone formation
Biocompatible	Yes	Yes



Characteristic	DSM Biomedical Dental Bone Graft (Subject Device)	Bio-OSS® (K033815: Predicate Device)
Reusable	Single Use Device	Single Use Device
Sterilization Method	Gamma Irradiation	Gamma Irradiation

Biocompatibility and Performance Data:

Material characterization, bench testing, biocompatibility testing, viral inactivation, and an animal study have been conducted to evaluate the performance characteristics and biological safety of DSM Biomedical Dental Bone Graft.

Material characterization of the DSM Biomedical Dental Bone Graft was completed in accordance with the FDA Guidance Document, *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* and *ASTM F 1581, Standard Specifications for Composition or Anorganic Bone for Surgical Implants*. Bench testing was completed to verify that the device can be hydrated and mixed in the provided packaging.

A canine intrabony defect animal study was performed to evaluate bone healing following treatment with the DSM Biomedical Dental Bone Graft 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, and Chronic Systemic Toxicity, and Implantation. Other safety testing included a viral inactivation study and residual chemical assessment. Results indicate that the device’s biocompatibility profile is acceptable.

Conclusion:

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