September 10, 2020

DSM Biomedical
Susan Pileggi
Senior Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19431

Re: K193212
Trade/Device Name: DSM Biomedical Dental Bone Graft Plus
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: August 17, 2020
Received: August 19, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193212

Device Name
DSM Biomedical Dental Bone Graft Plus

Indications for Use *(Describe)*
The DSM Biomedical Dental Bone Graft Plus 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.

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

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K193212

510(k) Summary

I. SUBMITTER

Submitter:	DSM Biomedical 735 Pennsylvania Drive Exton, PA 19341
Phone:	484-713-2100
Contact Person:	Susan Pileggi
Date Prepared:	September 10, 2020

II. DEVICE

Name of Device:	DSM Biomedical Dental Bone Graft Plus
Common/Usual Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material (21 CFR 872.3930)
Device Class:	II
Device Code:	NPM

III. PREDICATE DEVICE

Substantial equivalence is claimed to the following device:

- Bio-OSS® Collagen, K122894

The following device is referenced within the submission:

- DSM Biomedical Dental Bone Graft, K170245

IV. DEVICE DESCRIPTION

The DSM Biomedical Dental Bone Graft Plus is a non-pyrogenic porous bone mineral and collagen matrix for use in periodontal, oral, and maxillofacial surgery. The DSM Biomedical Dental Bone Graft Plus is composed of anorganic porcine bone granules combined with bovine collagen to form small cylinders. The device is provided in sizes ranging from 100 – 500mg. DSM Dental Bone Graft Plus is supplied sterile by gamma irradiation and is for single use only.

V. INDICATIONS FOR USE:

DSM Biomedical Dental Bone Graft Plus 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)

VII. COMPARISON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICE

The DSM Biomedical Dental Bone Graft Plus is substantially equivalent in terms of indications for use, material composition, technological characteristics, and performance characteristics to the predicate device, Bio-OSS® Collagen [Geistlich-Pharma] K122894. The subject device is substantially equivalent in terms of indications for use, technological characteristics and performance characteristics to the reference device, DSM Biomedical Dental Bone Graft K170245, but differs in material composition as the subject device contains collagen in addition to the anorganic bone material of the reference device. The devices are compared in the Table 1.

Table 1:

Characteristic	DSM Biomedical Dental Bone Graft Plus *(K193212: Subject Device)*	Bio-OSS® Collagen *(K122894: Predicate Device)*	DSM Biomedical Dental Bone Graft *(K170245: Reference Device)*
Indications for Use	DSM Biomedical Dental Bone Graft Plus 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).	Augmentation or reconstructive treatment of the alveolar ridge; filling of 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).	The DSM Biomedical Dental Bone Graft is indicated for use in 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	Human, oral, periodontal
Material Composition	Porcine-derived osteoconductive hydroxyapatite bone mineral with bovine collagen.	Bovine-derived osteoconductive hydroxyapatite bone mineral with porcine collagen	Porcine-derived osteoconductive hydroxyapatite bone mineral
Form	Cylinder	Block	Granules
Dimensions	100mg, 250mg, and 500mg	100mg, 250mg, and 500mg	0.5cc, 1.0cc, 2.5cc
Cumulative Pore Volume	1.6272 – 1.8329 mL/g	0.9524 – 1.1751 mL/g	1.3494mL/g

Characteristic	DSM Biomedical Dental Bone Graft Plus *(K193212: Subject Device)*	Bio-OSS® Collagen *(K122894: Predicate Device)*	DSM Biomedical Dental Bone Graft *(K170245: Reference Device)*
Pore Size Distribution	0.003 – 360.86µm	0.003 – 346.995µm	0.003 – 645µm
Pore Size Range	Primarily macropores	Primarily macropores	Primarily macropores
Porosity	73.42 – 77.26%	53.47 – 61.34%	65.97 – 68.74%
Package	Double sterile barrier consisting of an inner and outer tray	Double sterile barrier consisting of an inner and outer tray	Granules supplied in a single use sterilized vial.
Performance	Bone formation	Bone formation	Bone formation
Biocompatible	Yes (ISO 10993-1)	Yes	Yes (ISO 10993-1)
Reusable	Single Use Device	Single Use Device	Single Use Device
Sterility	Sterile, SAL 10-6 Gamma Irradiation (ISO 11137-1)	Sterile, SAL 10-6 Gamma Irradiation	Sterile, SAL 10-6 Gamma Irradiation (ISO 11137-1)
Pyrogencity	Non-pyrogenic (USP <85> and ISO 10993-11)	Non-pyrogenic	Non-pyrogenic (USP <85> and ISO 10993-11)

DSM Biomedical Dental Bone Graft Plus and the predicate device have identical indications for use and are for use in the same target population. They are provided in the same sizes. Both are sterilized by gamma irradiation and supplied in a double tray configuration. The materials are shown to be an osteoconductive hydroxyapatite bone mineral with a collagen component to aid in bone formation. The DSM Biomedical Dental Bone Graft Plus is derived from porcine bone and bovine collagen while the predicate device is derived from bovine bone and porcine collagen. This does not raise questions of substantial equivalence, as chemical and physical characteristics have been shown to be substantially equivalent in benchtop and animal testing.

VII. NON-CLINICAL TESTING DATA:

The following performance data was provided in support of the substantial equivalence determination.

Mechanical and Physical Testing

Material characterization of the DSM Biomedical Dental Bone Graft Plus was completed in accordance with the FDA Guidance Document, *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices*. Bench testing was completed to verify that the device can be hydrated and trimmed prior to implantation.

The packaging of DSM Dental Bone Graft Plus was designed to meet the requirements of ISO 11607-1. The product is gamma sterilized and has been validated per ISO 11137-1 and ISO 11137-2. Stability testing on the device included evaluations of appearance, mass, collagen characterization, and simulated use. The stability assessments verify that the passage of time did not affect the device performance, collagen characterization or package integrity.

Biocompatibility Testing

Biocompatibility testing was completed in accordance with the requirements of ISO 10993-1 for a permanent implant device with tissue/bone contact. Biocompatibility testing included the following biological effects:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Genotoxicity per ISO 10993-3
- Subacute Systemic Toxicity per ISO 10993-11
- Chronic Systemic Toxicity per ISO 10993-6
- Implantation per ISO 10993-6

Pyrogenicity testing per USP <85> and Rabbit Material Mediated Pyrogenicity testing per ISO 10993-11 have been completed to verify that the device is non-pyrogenic.

The porcine bone and bovine collagen are sourced in accordance with ISO 22442-2 and per the FDA Guidance Document, *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices*).

Viral inactivation studies per ISO 22442-3 and a residual chemical assessment per ISO 10993-17 were conducted.

Results indicate that the device's biocompatibility profile is acceptable.

Animal Testing

A canine intrabony defect animal study was performed to evaluate bone healing following treatment with the DSM Biomedical Dental Bone Graft Plus compared to the predicate device.

VIII. CONCLUSIONS

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