MedPark Co., Ltd.
Woojong Kim
Official Correspondent
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KOREA, SOUTH

October 13, 2023

Re: K231672
Trade/Device Name: S1
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: July 04, 2023
Received: July 17, 2023

Dear Woojong Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231672

Device Name
S1

Indications for Use *(Describe)*

S1 is intended for the following uses:
• Augmentation or reconstructive treatment of the alveolar ridge;
• Filling of infrabony periodontal defects
• Filling of defects after root resection, apicocectomy, 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); and
• 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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K231672

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Device Information

- Trade Name: S1
- Common Name: Bone Grafting Material
- Classification Name: Bone Grafting Material, Animal Source
- Device Panel: Dental
- Regulation Number: 21 CFR 872.3930
- Product Code: NPM
- Device Class: Class II
- Date Prepared: October/13/2023

Primary Predicate

The subject device is substantially equivalent to the following predicate device

- K122894, Geistlich Bio-Oss® manufactured by Geistlich Pharma AG

Reference Device

- K060732, MBCP Gel™ manufactured by BIOMATLANTE

Indication for Use

S1 is intended for the following uses:

- Augmentation or reconstructive treatment of the alveolar ridge

- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicocectomy, 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)

Device Description

S1 is intended for filling and augmentation of bony voids and gaps in maxillofacial surgery, implantology, and periodontology according to the intended use of the product.

S1 is serving as a matrix consisting of interconnected macro- and micropores. The material is porous and has inner surface area.

S1 is a mixture of Hydroxyapatite (HAp) and hydroxypropyl methylcellulose (HPMC). Hydroxyapatite (HAp) is made from bovine cancellous bone and is mineralized hydroxyapatite.

The bone particle size is 0.2 ~ 1.0mm for the powder type and 1.0 ~ 2.0 mm for the chip type.
S1 is packaged in vials and it is supplied sterile by gamma irradiation and is for single use only.

Summary of Technological Characteristics

Descriptive Information		Subject Device	Primary Predicate	Reference Predicate	Remark
K number		Unknown	K122894	K060732	
Manufacturer		MedPark Co., Ltd.	Geistlich Pharma Ag	BIOMATLANTE	
Model (Device name) / Type (Product name)		S1	Bio-Oss®	MBCP Gel™	
Product Code		NPM	NPM	LYC	Same
Regulation number		21CFR872.3930	21CFR872.3930	21CFR872.3930	Same
Intended Use		Intended for filling of bone defects and bone augmentation	Intended for filling of bone defects and bone augmentation	Intended for use as abone grafting material to fill, augment or reconstruct osseous bone defects in particular in periodontal oral/maxillofacial applications.	Same
Target Population		Adults (=> 22 years old)	Adults	Adults	Same
Anatomical site		Oral, periodontal	Oral, periodontal	Oral, periodontal	Same
Device Design	**Source Bone**	Bovine bone - Cancellous	Bovine bone - Cancellous	Biphasic Calcium Phosphate (60% Hydroxyapatite and 40% beta-Tricalcium Phosphate)	Similar
	Particle size range	0.2 – 1.0 mm 1.0 – 2.0 mm	0.25 – 1.0 mm 1.0 – 2.0 mm	0.5 – 1.0 mm	Similar
	Form	Granules	Granules	Granules (Putty type)	Same
	Reusable	Single Use only	Single Use only	Single Use only	Same
	Sterilization	Gamma Irradiation	Gamma Irradiation	Not identified	Same
Composition of Materials	**Chemical composition**	Hydroxyapatite with excipient vehicle of pharmaceutical grade quality (hydroxypropyl-methylcellulose)	Hydroxyapatite	Biphasic Calcium Phosphate with excipient vehicle of pharmaceutical grade quality (hydroxypropyl-methylcellulose)	Different (Biocompatibility, animal performance, and bench testing was performed to

					demonstrate substantial equivalence.)
Physical Properties	**Phase purity**	$Ca_5(PO_4)_3(OH)$ (≥95%)	$Ca_5(PO_4)_3(OH)$ (≥95%)	Not identified	Same
Shelf-life		2 years	3 years	Not identified	The Validation of Gamma Sterilization (Report No. 210107-E-2)
Performance		Bone formation	Bone formation	Bone formation	Same
Biocompatibility		Yes	Yes	Yes	Same
Indication for use		S1 is intended for the following uses: • 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); and • Filling of peri-implant	Bio-OSS® is intended for the following uses: • 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); and • Filling of peri-implant	MBCP Gel™ is intended for use as a bone grafting material to fill, augment or reconstruct osseous bone defects in aprticular in periodontal or oral/maxillofacial application. Theses defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MBCP Gel™ can generally be used for bone filling in closed cavities. MBCP Gel™ can be used with autogenous bone grafting materials. Typical uses include but are not limited to: • Periodontal/Infrabony defects • Ridge augmentation	Same

	defects in conjunction with products intended for Guided Bone Regeneration (GBR).	defects in conjunction with products intended for Guided Bone Regeneration (GBR).	• Extractions sites (implant preparation/placement) • Sinus lifts • Cystic cavities	

Similarity and Equivalence Discussion

Device characteristics with the Primary predicate device, such as intended use, general shape, sizes, structure, fundamental technologies and applied production method are equivalent.

- The new device has the same intended use (as discussed above).
- The main material of both the primary predicate device and S1 is the Hydroxyapatite (HAp).
- Through the Biocompatibility Test and Animal Performance Test, it was verified that the safety and performance of S1 are equivalent to the Primary Predicate device.

Difference Discussion

The difference compared to the primary predicate device(Bio-Oss® K122894) is that S1 is provided as a mixture of Hydroxyapatite (HAp) and hydroxypropyl methylcellulose (HPMC).

The hydroxypropyl methylcellulose (HPMC) used as an additive is pharmaceutical grade, and was also used in Reference Predicate Device.

Through the Biocompatibility Test and Animal Test, it was verified that the safety and performance of S1 were equivalent to that of the Primary Predicate device.

Non-clinical testing data

- The subject device was evaluated its substantial equvalence through physical tests according to ISO 13779-3:2018 as the below table.

Test Item	Methods/Standards	Criteria	Result
Crystallinity Ratio	ISO 13779-3	The crystallinity ratio should be more than 95%.	100 %
Ca/P ratio	ISO 13779-3	Ratio of calcium (Ca) and phosphate (P) must be 1.66±0.1.	1.66
Hydroxyapatite(HAp) Contents	ISO 13779-3	The content of Hydroxyapatite(HAp) should be more than 97 wt%.	100 wt%
Heavy metals	ASTM F1581-08, ISO 13779-3	As ≤ 3 mg/kg Pb ≤ 30 mg/kg Hg ≤ 5 mg/kg Cd ≤ 5 mg/kg (The total contents of heavy metal shall be less than 50 mg/kg.)	As: Not Detected Pb: 0.8 mg/kg Hg: 0.012 mg/kg Cd: Not Detected

- Sterilization Validation Test according to ISO 11137-1:2006 , ISO 11137-2:2013, ISO 11137-3:2017
- Packaging and shelf-life testing according to ASTM F1980-16, ASTM F1980, ASTM F88-15, ASTM F1140, ASTM F2096, ASTM D4169-22, ISO 11607-1:2019, ISO 11607-2:2019, ASTM F1929-15, ISO 13779-3:2018, ISO 11737-2:2019
- Biocompatibility testing according to ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010 and ISO 10993-11:2017, ISO 10993-12:2012, ISO 10993-23:2021, USP (151)
- Medical devices utilizing animal tissues and their derivatives according to ISO 22442-1:2020, ISO 22442-2:2020
- Virus Inactivation Testing according to ISO 22442-3:2007

S1 was the subject of the full range of biocompatibility test recommended in the FDA's "Class II Special Controls Guidance Documents: Dental Bone Grafting Devices" and in accordance with ISO 10993-1. Test results confirmed product safety. In addition, virus inactivation study was conducted. Further, the product is sterilized to achieve a sterility assurance level SAL 1 X10-6.

The results of these studies confirm the substantial equivalence of S1 to its predicate devices.

Animal Test

The performance of the beagle mandibular defect model was compared to the performance of the predicate device, Bio-Oss®. Radiographic, Micro CT, Histology and Histomorphometry analyses were conducted following implantation at 4, 8, and 12 weeks for the subject device, predicate device and negative control.

The predicate device Bio-Oss® and the subject device S1 were compared in the preclinical study, and the results demonstrated substantially equivalent performances under intended uses.

Eventually, the majority of the device will be resorbed by 24 months or more, and was found to be similar to the predicate device Bio-Oss®.

Conclusion

S1 constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to its predicate devices.