



June 16, 2026

Medpark Co., Ltd.
Kyonghoon Shin
Prcc
24, Nakdong-Daero 1570 Beon-Gil, Buk-Gu
Busan, 46504
Republic Of Korea

Re: K253723

Trade/Device Name: Boss
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: May 14, 2026
Received: May 15, 2026

Dear Kyonghoon Shin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

510(k) Number (if known)
K253723

Device Name
BOSS

Indications for Use (Describe)

- 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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Device Information

- Trade Name: BOSS
- 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: June/16/2026

Primary Predicate

The subject device is substantially equivalent to the following predicate device

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


Reference Device

- K231672, S1 manufactured by MedPark Co., LTD

Indication for Use

BOSS is intended for the following uses:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects

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- 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)

Device Description

BOSS 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.


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

BOSS consists of Hydroxyapatite (HAp).

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.

BOSS is packaged in vials and it is supplied sterile by gamma irradiation and is for single use only.


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Summary of Technological Characteristics

Descriptive Information		Subject Device	Primary Predicate	Reference Predicate	Remark
K number		K253723	K122894	K231672	
Manufacturer		MedPark Co., Ltd.	Geistlich Pharma Ag	MedPark Co., Ltd.	
Model (Device name) / Type (Product name)		BOSS	Bio-Oss®	S1	
Product Code		NPM	NPM	NPM	Same
Regulation number		21CFR872.3930	21CFR872.3930	21CFR872.3930	Same
Target Population		Adults	Adults	Adults	Same
Anatomical site		Oral, periodontal	Oral, periodontal	Oral, periodontal	Same
Device Design	Source Bone	Bovine bone - Cancellous	Bovine bone - Cancellous	Bovine bone - Cancellous	Similar
	Particle size range	0.2 – 1.0 mm 1.0 – 2.0 mm	0.25 – 1.0 mm 1.0 – 2.0 mm	0.2 – 1.0 mm 1.0 – 2.0 mm	Similar
	Form	Granules	Granules	Granules	Same
	Reusable	Single Use only	Single Use only	Single Use only	Same
	Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same
Composition of Materials	Chemical composition	Hydroxyapatite	Hydroxyapatite	Hydroxyapatite 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%)	Ca ₅ (PO ₄) ₃ (OH) (≥95%)	Same

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Shelf-life	5 years	3 years	2 years	Different BOSS has real-time stability report supporting a 5-year shelf life.
Biocompatibility	Yes	Yes	Yes	Same
Indication for use	<p>BOSS is intended for the following uses:</p> <ul style="list-style-type: none"> • 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 defects in conjunction with products intended for Guided Bone Regeneration (GBR). 	<p>Bio-OSS® is intended for the following uses:</p> <ul style="list-style-type: none"> • 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 defects in conjunction with products intended for Guided Bone Regeneration (GBR). 	<p>S1 is intended for the following uses:</p> <ul style="list-style-type: none"> • 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 defects in conjunction with products intended for Guided Bone Regeneration (GBR). 	Same

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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 BOSS is the Hydroxyapatite (HAp).
- Through the Biocompatibility Test and Animal Performance Test, it was verified that the safety and performance of BOSS are equivalent to the Primary Predicate device.

Non-clinical testing data

- The subject device was evaluated its substantial equivalence 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/Amd.2:2018 , ISO 11137-2:2013, ISO 11137-3:2017, ISO 11737-1:2018, ISO 11737-2:2019
- Packaging and shelf-life testing according to ISO 11607-1:2019, ISO 11607-2:2019, ASTM F1980-16, ASTM F1140/F1140M-13), ASTM F1929-15, ASTM F2096-11, ASTM F88/F88M-15, ASTM D4169-22, ISO 13779-3:2018, USP

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- 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, 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

BOSS 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 BOSS to its predicate device.

Animal Test

The performance of the beagle mandibular defect model (15 mm Length/mesiodistally x 10 mm Depth/apicocoronally, saddle type defect) 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 to assess bone formation, device resorption and local effects of implantation per ISO10993-6.

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

Conclusion

BOSS 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.