



September 25, 2026

Hyundai Bioland Co., Ltd.
Seo Yeji
Official Correspondent
162, Gwahaksaneop 3-Ro, Ochang-Eup, Cheongwon-Gu
Cheongju-Si, Chungcheongbuk-do 28125
REPUBLIC OF KOREA

Re: K254210

Trade/Device Name: Rebohil (bgm-1, Bgm-2, Bgm-3, Bgm-4, Bgm-5)
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: August 25, 2026
Received: August 26, 2026

Dear Seo Yeji:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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)

K254210

Device Name

REBOHIL (BGM-1, BGM-2, BGM-3, BGM-4, BGM-5)

Indications for Use (Describe)

REBOHIL 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 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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HYUNDAI BIOLAND Co., Ltd.

162 Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, 28125 Republic of Korea
TEL: +82-43-240-8633 FAX: +82-43-240-8699
Website: www.hyundaibiland.co.kr



The assigned 510(k) Number: K254210

01. Date of Preparation: 2026.09.25

02. Applicant

Company name: HYUNDAI BIOLAND Co., Ltd.
Address: 162, Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu, Cheongju-si,
Chungcheongbuk-do, 28125, Republic of Korea
TEL: +82 43 240 8633
FAX: +82 43 240 8699
Email: bio_ra@hyundaibiland.co.kr

03. Submission Correspondent

Yeji Seo
HYUNDAI BIOLAND Co., Ltd.
Address: 162, Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu, Cheongju-si,
Chungcheongbuk-do, 28125, Republic of Korea
TEL: +82 43 240 8649
FAX: +82 43 240 8694
Email: bio_ra@hyundaibiland.co.kr

04. Subject Device Identification

Trade Name: REBOHIL
Common Name: Bone grafting material
Classification Name: Bone grafting material, animal source
Product Code: NPM
Panel: Dental surgery
Regulation Number: 21 CFR 872.3930
Device Class: Class II

05. Indication for use

- REBOHIL 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 Bone Regeneration(GBR).
 - Filling of peri implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

06. Predicate devices and Reference devices

Predicate device
510(k) Number: K142040
Device Name: OCS-B Collagen®

Manufacturer: NIBEC Co., Ltd.

07. Device Description

REBOHIL (Dental bone graft) is composed of 90% anorganic bone mineral granules derived from porcine cancellous bone and 10% collagen from porcine hide in a powder form, which is derived from veterinary certified pigs and purified and non-cross linked. The REBOHIL is a bone graft obtained by a standardized controlled manufacturing process.

The REBOHIL is packed in a double sterile barrier system consisting of an inner PC (Polycarbonate) bowl and an outer PET (Polyethylene terephthalate) blister. The packaging material composed of a transparent side and Tyvek side and is easy to use by open system of easy peel type. It is easy to check the REBOHIL, because one side of packaging is transparent closed by double packing system in order to protect REBOHIL from microbial formation. Then this packaged REBOHIL is sterilized by ethylene oxide gas.

The surgical procedure consists to preserve ridge dimensions in post-extraction sockets as well as in the treatment of defects in the alveolar process. Grafting materials and barrier membranes to conduct and direct the growth of new bone at defect sites. Material is placed into a bone deficient area, maintaining space and conducting formation of new bone.

The REBOHIL is available to the United States market in 5 version: 0.15g, 0.25g, 0.5g, 1.0g, 2.0g. They are supplied sterile and intended for single use only.

Model No.	Volume	Packaging (ea/box)
BGM-1	0.15g	1
BGM-2	0.25g	1
BGM-3	0.5g	1
BGM-4	1.0g	1
BGM-5	2.0g	1

[Material Composition]

Material	Molecular formula	Percentages	Specification	Standard
Bone	Hydroxyapatite	90±5%	Origin: derived from porcine bone	ISO13779-3 ASTM F1185
Collagen	Type I Collagen	10±1%	Origin: derived from porcine hide	ASTM F2212

08. Performance data

08.1 Bench testing

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

No.	Test Item	Description and Discussion
1	Appearance	The appearance test was to check damage or breakage, and foreign materials by inspecting the appearance of the subject and predicate device. Both of devices were no defect at the sample.
2	Weight	Both of subject and predicate device were checked the weight of product with weighing scale. Both of them did not exceed the allowance.
3	pH	The pH test compares the amount of acid or base required to neutralize the device extract with that required for the blank extract to evaluate buffering capacity. Both of devices were not exceed an allowance.
4	Heavy metal	The heavy metal analysis was to check the limit of cadmium, lead, arsenic and mercury through heavy metal limit test. Both of subject and predicate device did not exceed the allowance.
5	Amino acid	The Amino acid analysis was to check the amino acid composition of devices with HPLC. Both of subject and predicate device had similar amino acid composition each other.
6	Collagen purity	The collagen purity test was evaluated through the SDS-PAGE to confirm the presence of type I collagen, since both of subject and predicate device consist of hydroxyapatite and type I collagen. We confirmed that the type I collagen of subject and predicate devices were not denatured or degraded in comparison to the type I collagen standard.
7	Carbohydrate content	The carbohydrate content test was to check residual carbohydrate content in devices. The carbohydrate content was conducted by UV/VIS. Both of subject and predicate device met the criteria of less than 2.0%.
8	Sterility	The sterility test was to verify that sterile packing of sterilized device is kept sterilization, and whether device sterilization has been thoroughly completed by bacterial and fungal testing for sterility according to ISO 11737-2. Both of subject and predicate device showed negative results for bacterial & fungus.
9	Collagen concentration	The collagen concentration test was to check the collagen content of device, since both of subject and predicate device consist of hydroxyapatite and type I collagen. The test was conducted through ASTM F2212-20 and the subject device did not exceed the acceptance criteria of 10±1%.

10	Residue on ignition	The residue on ignition test was to check the remaining minerals in device through residue on ignition test. Both of subject and predicate device had a similar results.
11	Hydroxyapatite analysis	The hydroxyapatite analysis was evaluated according to ISO 13779 to identify hydroxyapatite of devices. The identification of hydroxyapatite was performed by X-ray diffraction (XRD). The subject device had been identified as hydroxyapatite equivalent to predicate device.
12	Ca/P ratio	The Ca/P ratio test was to evaluate ratio of calcium and phosphorus through XRD according to ISO 13779. Both of subject and predicate device had a similar Ca:P atomic ratio between 1.5 and 2.0.
13	Porosity	The porosity, which is related to providing space where new tissue and blood vessel grow, was to check the structural characteristics of device through mercury intrusion porosimetry. The subject device had a porosity similar to that of predicate device.
14	Loss on drying	The Loss on drying was determined by measuring the decrease in sample weight after drying. Both the subject and predicate devices met the predefined acceptance criterion of not more than 20%.
15	Water binding capacity	The water binding capacity test was to evaluate the maximum water binding capacity that a devices can contain. The subject device had a higher binding capacity compared to predicate devcie.
16	Lipid content	The lipid content test was to evaluate the residual lipid content of devices with absorbance. The subject device had a lower lipid compared to predicate device.
17	LAL test	The LAL test was to confirm the biological safety of devices through endotoxin test. The results showed that it enables us to judge that removal of endotoxin was performed smoothly in the manufacturing process and both of subject and predicate confirmed the biological safety.
18	GAG test	The GAG test was to evaluate whether the decellularization process has been effectively performed or not by checking the contents of glycosaminoglycan. The subject device had a lower GAG conent than predicate device.

08.2 Biocompatibility

Biocompatibility testing was conducted for the subject device in accordance with the applicable ISO 10993 standards. The device was non-cytotoxic, non-sensitizing, and non-irritating and did not demonstrate evidence of acute systemic toxicity, material-mediated pyrogenicity, or genotoxicity under the conditions of the respective tests. The subchronic toxicity and implantation study demonstrated an acceptable local and systemic biological response. The results support the biological safety of the subject device for its intended use.

No.	Test Item	Standard	Result
1	Biological Safety Evaluation Plan	ISO 10993-1	Satisfied
2	Biological Risk Assessment	ISO 10993-1	Satisfied
3	Cytotoxicity	ISO 10993-5	Satisfied
4	Sensitization	ISO 10993-10	Satisfied
5	Oral Mucosal Irritation	ISO 10993-23	Satisfied
6	Acute Systemic Toxicity	ISO 10993-11	Satisfied
7	Material-Mediated Pyrogenicity	ISO 10993-11	Satisfied
8	Genotoxicity : Bacterial Gene Mutation Assay	ISO 10993-3	Satisfied
9	Genotoxicity: Mouse Lymphoma Assay	ISO 10993-3	Satisfied
10	Subchronic Toxicity and Implantation	ISO 10993-11 & ISO 10993-6	Satisfied

08.3 Sterilization and Shelf-life

- Validation of sterilization per ISO 11135
- Validation of shelf life per ASTM F1980 using accelerated and real-time aged samples
- Validation of packaging per ISO 11607-2
- Validation of shipping per ISTA 3A
- Physicochemical characterization per ASTM F1581

08.4 Animal tissue

- Viral inactivation per ISO 22442-3

08.5. Performance Testing – Animal

Animal study was conducted over 4, 8 12 and 24weeks in 20 beagle dogs to evaluate the in vivo efficacy of the REBOHIL developed as a bonegraft. OCS-B Collagen® was used as a positive control group and REBOHIL was used as a study group. After operation, clinical signs were monitored, and radiographic examinations were performed. After the animal sacrificed, micro-CT image analysis, histomorphometrical and histological examinations were performed on the harvested tissues.

In this study, REBOHIL was applied on the one wall intrabony alveolar bone defect on the mandible of beagle dogs and the periodontal regeneration effects of 4, 8, 12 and 24 weeks were evaluated . When comparing REBOHIL with OCS-B Collagen®, it showed sufficient bony regeneration effect on the one wall intrabony alveolar bone defect on the mandible of beagle dogs.

08.6. Performance Testing – Clinical

No human clinical trials were performed in support of this submission.

HYUNDAI BIOLAND Co., Ltd.

162 Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, 28125 Republic of Korea
TEL: +82-43-240-8633 FAX: +82-43-240-8699
Website: www.hyundaibiland.co.kr



09. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	SUBJECT Device REBOHIL	PREDICATE Device OCS-B Collagen® (K142040)	Equivalence Discussion
Classification Name	Bone grafting Material, Animal Source	Bone grafting Material, Animal Source	Identical
Class	Class II	Class II	Identical
Regulation Number	21 CFR 872.3930	21 CFR 872.3930	Identical
Product code	NPM	NPM	Identical
Indication for Use	REBOHIL 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 Bone Regeneration (GBR). - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).	OCS-B Collagen® is recommended 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).	Equivalent Predicate device indications encompass all the subject device indications.
Materials	Anorganic derived osteoconductive hydroxyapatite, Collagen	Anorganic derived osteoconductive hydroxyapatite, collagen	Equivalent
Source of bone	Porcine	Bovine	Similarities: Both devices are composed of hydroxyapatite. Differences: The subject device is derived from porcine, while the predicate device is derived from bovine. Equivalent Discussion: Although the bone source is different, the chemical composition is the same as hydroxyapatite.
Source of collagen	Porcine skin	Porcine skin	Equivalent
Dosage form	Powder (Granule)	Block	Similarities: The available forms of the subject device are within the specifications of

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Cheongju-si, Chungcheongbuk-do, 28125 Republic of Korea
TEL: +82-43-240-8633 FAX: +82-43-240-8699
Website: www.hyundaibiland.co.kr



			predicate device Differences: The subject device is a granule form, but predicate device is a block form. Equivalent Discussion: The form is different from granule vs block, but it does not affect the product performance
Bone particle size range	0.5 mm to 1.0 mm	0.1 mm to 1.0 mm	Similarities: The both of devices has similar bone particle size. Differences: The subject device has more narrow range of bone particle range than predicate device. Equivalent Discussion: Both devices are provided in clinically relevant bone particle sizes for intra-oral surgical procedures
Product Size	150 mg, 250 mg, 500 mg, 1,000 mg, 2,000 mg	50 mg, 100 mg, 250 mg, 500 mg	Similarities: Both of subject and predicate devices has different sizes available to suit various conditions. Differences: The subject device has a larger product sizes than predicate device. Equivalent Discussion: Both devices are provided in clinically relevant sizes for intra-oral surgical procedures
Biocompatibility	Biocompatible for the cleared indications for use	Biocompatible for the cleared indications for use	Equivalent
Packaging	Double sterile barrier: 1st packaging: Tray (Polycarbonate), Lid (Tyvek) 2nd packaging: Blister (Polyethylene terephthalate), Lid (Tyvek)	Double sterile barrier: Packed in a double sterile barrier system consisting of an inner and an outer blister	Similarities: Both devices have a two layers for packaging. Differences: The subject device is composed of plastic bowl in blister, while the predicated device consists of double blister. Equivalent Discussion: Both devices are provided in two layers of sterile barrier packaging. Both devices facilitate the aseptic delivery of the sterile device into the sterile surgical field.
Sterilization	Ethylene Oxide Gas	Gamma Irradiation	Similarities: Both devices are sterile device. Differences:

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			The subject device was sterilized with E.O gas, while the predicate device was sterilized with gamma irradiation. Equivalent Discussion: Both the subject and predicate devices achieve a sterility assurance level of 10^{-6}
Single Use / Reuse	Single use only	Single use only	Identical
Pyrogenic	Non-pyrogenic	Non-pyrogenic	Identical
Shelf-Life	36 months	36 months	Identical

10. Conclusion

The subject and predicate devices have the same intended use/indications for use and substantially similar technological characteristics and principles of operation. In addition, minor technological differences between the two products do not affect the product performance, as supported by the results of the non-clinical data provided within the 510(k) submission, as summarized above. Therefore, the subject device, REBOHIL, is substantially equivalent to the predicate device, K142040.