October 2, 2020

Sk bioland Co., Ltd.
℅ Sanglok Lee
Manager
WISE COMPANY Inc.
RM #303, The Sky Balley-303, 142, Gasan Digital 1-Ro
Geumcheon-gu, Seoul 08507
Republic of Korea

Re: K200623
Trade/Device Name: OssGuide
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: September 1, 2020
Received: September 3, 2020

Dear Sanglok Lee:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200623

Device Name
OssGuide

Indications for Use *(Describe)*
OssGuide is recommended for:
- Simultaneous use of GBR-membrane (OssGuide) and implants;
- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Aid regeneration of bone defects after root resection, cystectomy, removal of retained teeth;
- Guided bone regeneration in dehiscence defects

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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SK bioland Co., Ltd.
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510(k) Summary – K200623

01. Date of Submission: October 2, 2020

02. Applicant

Company name: SK bioland Co., Ltd.
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03. Submission Correspondent

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04. Proposed Device Identification

Trade Name: OssGuide
Common Name: Absorbable collagen membrane
Classification Name: Barrier, Animal Source, Intraoral
Product Code: NPL
Panel: Dental
Regulation Number: 21 CFR 872.3930
Device Class: Class II

05. Indication for use

OssGuide is recommended for:

- Simultaneous use of GBR-membrane (OssGuide) and implants;
- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Aid regeneration of bone defects after root resection, cystectomy, removal of retained teeth;
- Guided bone regeneration in dehiscence defects

06. Predicate devices

510(k) Number: K050446
Device Name: BIO-GIDE®
Manufacturer: Ed. Geistlich Soehne Ag fuer Chemische Industrie

07. Device Description

OssGuide (Absorbable collagen membrane) is made of purified collagen without further cross-linking or chemical treatment. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. The *OssGuide* is a collagen membrane obtained by a standardized controlled

manufacturing process. The *OssGuide* has a porous and fibrous microstructure that prevents the ingrowth of fibrous tissue into the bone defect.

OssGuide is packed by a packaging material composed of a transparent side and an aluminium side and is easy to use by open system of easy peel type. It is easy to check the *OssGuide*, because one side of packaging is transparent closed by double packing system in order to protect *OssGuide* from microbial formation and moisture penetration. Then this packaged *OssGuide* is sterilized by gamma irradiation. The packaging contains the *OssGuide* and one Tyvek material template.

The surgical procedure consists of placing of an occlusive physical barrier between the connective tissue and the bone defect to prevent the migration of the epithelial and connective tissue cells into the defect. The periodontal defect or bone defect is exposed by a mucoperosteal flap and basic surgical procedures (e.g. curettage) are performed. The clinician should perform thorough debridement and efficient planing of the defect. Space-making material such as autologous bone or bone substitute may be used to fill the defect. ***OssGuide*** can be placed either dry or hydrated. ***OssGuide*** can be trimmed to the size and shape of the defect in a dry or wet state using scissors. A piece of sterile Tyvek may be used as a template for membrane sizing and trimming. ***OssGuide*** should overlap the walls of the defect by at least 2 mm to allow complete bone contact and to prevent gingival connective tissue invasion below the material. The membrane may be secured in place with sutures, tacks, or by means of sufficient contact with the mucoperiosteal flap to avoid displacement and micro motion during healing. To facilitate proper healing, ensure that there is tension-free primary closure of the soft tissue flap covering the membrane.

OssGuide a bioresorbable scaffold that is eventually resorbed and replaced by host tissue. *OssGuide* is substantially resorbed within 24 weeks after implantation.

The ***OssGuide*** is available to the United Sates market in 5 sizes as shown below. They are supplied sterile and intended for single use only.

Model No.	Size	Packaging (ea/box)
TG-1	15 x 20mm	1
TG-2	20 x 30mm	1
TG-3	30 x 40mm	1
TG-4	15 x 30mm	1
TG-5	25 x 25mm	1

08. Non-Clinical Test Conclusion

The determination of substantial equivalence was based on an assessment of non-clinical performance data obtained from *in vitro* characterization studies, an *in vivo* animal study, biocompatibility testing.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate device in biochemical, physicochemical, mechanical properties. The test results demonstrated that the proposed device complies with the following standards:

- Physicochemical Characterization per ASTM F2212
- Tensile strength testing
- Suture pull-out strength testing

Validation of packaging, shelf life, transport and sterilization are performed as following:

- Validation of Primary and Secondary barrier packaging per ISO 11607-2
- Validation of shelf life per ASTM F1980 using age accelerated and real-time aged samples
- Validation of transport packaging per ASTM D4169
- Validation of sterilization parameters per ISO 11137

Biocompatibility of the subject device was evaluated in accordance with ISO 10993-1 as followings:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10093-10
- Subchronic Toxicity per ISO 10993-11
- Genotoxicity per ISO 10993-3
- Implantation per ISO 10993-6
- Material mediated pyrogenicity per USP

Results indicate that the device's biocompatibility profile is acceptable.
The pyrogenicity of ***OssGuide*** was tested *in vivo* using the Rabbit Pyrogen Test as per USP <151>, and the test article was judged as nonpyrogenic. As a pyrogenicity sample testing plan, the endotoxin (LAL) testing will be conducted on every batch of ***OssGuide*** products.

The manufacturing control of animal tissue components is performed as following:

- Controls on sourcing, collection, and handling per ISO 22442-2
- Viral Inactivation per ISO 22442-3

Animal study was conducted in the alveolar bone defect of beagle dogs to evaluate the *in vivo* performance and degradation of the ***OssGuide,*** supporting substantial equivalence. The study was conducted on 20 animals followed for 4, 8, 12 and 24 weeks. When comparing ***OssGuide*** with the predicate device, Bio-Gide with Bio-Oss bone graft material as a positive control, it showed sufficient GBR effect for the alveolar bone regeneration on the alveolar bone defect of beagle dogs. ***OssGuide*** maintained their contour until 8 weeks, lost most of its integrity after 12 weeks, and disappeared by biodegradation at 24 weeks.

09. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	SUBJECT Device OssGuide	PREDICATE Device BIO-GIDE® (K050446)	Equivalence Discussion
Product code	NPL	NPL	**Identical**
Regulatory class	Class Ⅱ	Class Ⅱ	**Identical**
Regulation Number	21 CFR 872.3930	21 CFR 872.3930	**Identical**
Intended use	OssGuide is recommended for;	Bio-Gide® is recommended for;	**Equivalent** The indications for the subject device are a subset

	- Simultaneous use of GBR-membrane (OssGuide) and implants; - Augmentation around implants placed in immediate extraction sockets; - Augmentation around implants placed in delayed extraction sockets; - Localized ridge augmentation for later implantation; -Alveolar ridge reconstruction for prosthetic treatment; - Aid regeneration of bone defects after root resection, cystectomy, removal of retained teeth; - Guided bone regeneration in dehiscence defects	- Simultaneous use of GBR-membrane (BIO-GIDE) and implants; - Augmentation around implants placed in immediate extraction sockets; - Augmentation around implants placed in delayed extraction sockets; - Localized ridge augmentation for later implantation; -Alveolar ridge reconstruction for prosthetic treatment; - Aid regeneration of bone defects after root resection, cystectomy, removal of retained teeth; - Guided bone regeneration in dehiscence defects; and - Guided tissue regeneration procedures in periodontal defects.	of the indications for the predicate devices.
Mode of Action	OssGuide functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled, resorbed, and replaced by host tissue.	Bio-Gide® functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled, resorbed, and replaced by host tissue.	**Identical**
Operating Principles	Cell-Occlusive Implantable Resorbable Biocompatible	Cell-Occlusive Implantable Resorbable Biocompatible	**Identical**
Material	Purified collagen	Purified collagen	**Identical**
Collagen source	Porcine pericardium	Porcine peritoneum	**Equivalent** Using the tissue extracted from porcine is the same, but the parts of tissue used are different.
Form	Membrane	Membrane	**Identical**
Structure	Bilayer structure	Bilayer structure	**Identical**
Color	White to off-white	White to off-white	**Identical**
Product Size	15x20mm, 20x30mm, 30x40mm, 15x30mm, 25x25mm	13x25mm, 25x25mm, 40x50mm	**Equivalent** Both devices are provided in clinically relevant sizes for intra-oral surgical procedures

Resorption time	Substantially resorbed by 24 Weeks	Substantially resorbed by 24 Weeks	**Identical**
Sterilization	Gamma Irradiation	Gamma Irradiation	**Identical**
Singe Use/ Reuse	Single use only	Single use only	**Identical**
Packaging	Double pouch pack	Double blister pack	**Identical**
Shelf -life	36 months	36 months	**Identical**

The proposed device, OssGuide, is determined to be Substantially Equivalent **(SE)** to the predicate devices, BIO-GIDE® (K050446) in respect of safety and effectiveness.