Orthocell Ltd
Alison Carleton
Regulatory Affairs Associate
Building 191 Murdoch University, South St, MURDOCH
Perth, West Australia 6150
AUSTRALIA

Re: K201241
Trade/Device Name: Striate+ ™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: December 11, 2020
Received: December 14, 2020

Dear Alison Carleton:

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,

Andrew I. Steen -S

Andrew Steen
Assistant 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)*
K201241

Device Name
Striate+™

Indications for Use *(Describe)*
Striate+™ is indicated for use in:
- augmentation around implants placed in immediate extraction sockets
- augmentation around implants placed in delayed extraction sockets
- filling of bone defects after root resection or removal of retained teeth
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in intrabony periodontal 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.

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510(k) Summary

Striate+™

I. SUBMITTER

Orthocell Ltd
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South Street, Murdoch WA 6150
AUSTRALIA
Phone + 61 8 9360 6268

Contact Person: Dr. Alison Carleton
Date prepared: 11 January 2021

II. DEVICE

Device Name:	Striate+™
Common Name:	Implantable Collagen Membrane
Regulation:	21 CFR 872.3930 Bone grafting material
Regulatory Class:	Class II
Product Code:	NPL (Barrier, animal source, intraoral)
Panel:	Dental

III. PREDICATE DEVICE

Substantial equivalence is claimed to:

Geistlich Bio-Gide® K042197

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Striate+™ is an implantable biocompatible, sterile, resorbable collagen barrier membrane intended for use in dental guided bone and guided tissue regeneration procedures.

Striate+™ has a bilayer structure (rough and smooth sides). The rough side, placed facing the bone defect, is composed of a loose distribution of collagen bundles allowing ingrowth of bone forming cells. The smooth side, facing the soft tissue, is composed of densely packed collagen bundles forming a barrier to soft tissue ingrowth into the defect. Striate+™ is supplied dry and can be easily trimmed to the required size. The collagen material becomes soft and pliable when hydrated allowing conformation to the repair site. Striate+™ has sufficient mechanical strength to be sutured in place, if required, and is gradually resorbed into the surrounding tissue. Striate+™ is sterilized with gamma radiation. Striate+™ is provided in the following sizes: 15 mm x 20 mm, 20 mm x 30 mm, 30 mm x 40 mm, 40 mm x 50 mm.

V. INDICATIONS FOR USE

Striate+™ is indicated for use in:

- Augmentation around implants placed in immediate extraction sockets
- Augmentation around implants placed in delayed extraction sockets
- Filling of bone defects after root resection or removal of retained teeth
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in intrabony periodontal defects

The indications for use statement of Striate+™ is not identical to the predicate device (Table 1); however, the differences do not alter the intended therapeutic use of the subject device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use as a barrier membrane in guided bone and guided tissue regeneration procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Striate+™ and the predicate device have the same intended use as barrier membranes in guided tissue and guided bone regeneration procedures. Both the subject and predicate devices are derived from porcine tissue and have the same technological and biochemical characteristics, associated with their intended use (Table 1).

Differences in technology, including raw material tissue sources or manufacturing processes, that exist between the subject and predicate devices have been demonstrated not to affect the substantial equivalence through comparative performance data. The difference in the size variants between the subject and predicate devices are not considered to be different enough to have any effect on function, useability or substantial equivalence as they are all clinically relevant sizes for intra-oral surgical procedures.

Table 1 Device Comparison – Striate+™ and Bio-Gide® barrier membranes		
Device name	**Striate+**	**Bio-Gide® (K042197)**
Intended purpose	Striate+ is a biocompatible, sterile, resorbable collagen barrier membrane intended for use in guided bone and tissue regeneration.	Bio-Gide® is a biocompatible, sterile, resorbable bilayer collagen membrane for guided tissue and bone regeneration.
Indications for use	Striate+™ is indicated for use in: • augmentation around implants placed in immediate extraction sockets • augmentation around implants placed in delayed extraction sockets • filling of bone defects after root resection or removal of retained teeth • guided bone regeneration in dehiscence defects; and • guided tissue regeneration procedures in intrabony periodontal defects.	Bio-Gide® is indicated for: • 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; • filling 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.
Technological characteristics	• Bilayer structure • Suturable • Absorbent • Retains tensile strength when wet • Cell-occlusive • Resorbed in 3-6 months	• Bilayer structure • Suturable • Absorbent • Retains tensile strength when wet • Cell-occlusive • Resorbed in 3-6 months
Form	Flexible, dry, white sheet of material with distinct smooth and rough sides	Flexible, dry, white sheet of material with distinct smooth and rough sides
Size variants	• 15 mm x 20 mm • 20 mm x 30 mm • 30 mm x 40 mm • 40 mm x 50 mm	• 13 mm x 25 mm • 25 mm x 25 mm • 40 mm x 50 mm
Composition	Type I collagen	Type I collagen
Biocompatibility	• Biocompatible (ISO 10993) • Biocompatible (animal model of GBR)	• Biocompatible (ISO 10993) • Biocompatible (animal model of GBR)
Source material	Porcine collagen	Porcine collagen
Packaging	Double PETG trays with Tyvek® seals	Double PETG trays with Tyvek® seals
Sterilization	Gamma irradiation (SAL 10^{-6})	Gamma irradiation (SAL 10^{-6})
Shelf life	36 months	36 months
Reusability	Single use	Single use

VII. PERFORMANCE DATA

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

- Biocompatibility (ISO 10993-1)
- Viral Inactivation (ISO 22442)
- Sterilization Validation (ISO 11737-1, ISO 1137-2, ISO 11737-3)
- Shelf Life Validation (real-time) (ASTM F2212, ASTM F2150)
- Endotoxin Level (USP <161>, USP <85>)
- Tensile strength
- Suture pull-out strength
- Absorbency/Wettability
- Thickness
- Composition (amino acid analysis, total protein, GAG, lipid and DNA content, SDS-PAGE, Western Blot Analysis)
- SEM imaging

The bench testing demonstrated that the subject and predicate device displayed equivalent characteristics with respect to structure, composition, tensile strength, suturability, thickness and absorbency.

Biocompatibility

The biocompatibility evaluation for Striate+™ was conducted according to International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" as recognized by the FDA. The battery of tests included the following:

- Cytotoxicity
- Irritation
- Sensitization
- Local and systemic toxicity
- Genotoxicity
- Pyrogenicity

Animal Study

Pre-clinical animal studies conducted in a large animal intra oral model comparing Striate+™ and the predicate device at 4, 8 and 12 weeks demonstrate that both are cell-occlusive, preventing ingrowth of epithelial cells into the bone defect, and that the subject and predicate device are fully resorbable and biocompatible. Bone formation, inflammatory response and membrane degradation rate of Striate+™ was no different to the predicate when evaluated by micro-computed tomography, histomorphometric analysis and histological analysis, providing in vivo evidence for substantial equivalence of the two devices.

IX. CONCLUSION

The intended use, principles of operation, and technological characteristics of Striate+™ are substantially equivalent to the predicate device Bio-Gide (K042197). Any differences observed between the subject and predicate device were minor and would not be expected to impact the safety and performance of the device. Therefore, it can be concluded that Striate+™ is substantially equivalent to the predicate Bio-Gide®.