SigmaGraft Inc.
Elcin Chang
General Manager
575 Sally Place
Fullerton, California 92831

08/17/23

Re: K223912
Trade/Device Name: InterCollagen® Guide
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: July 26, 2023
Received: July 26, 2023

Dear Elcin Chang:

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,

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)*
K223912

Device Name
InterCollagen® Guide

Indications for Use *(Describe)*
InterCollagen® Guide alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration.

- in the context of a treatment of fenestration defects
- in case of dehiscence defects
- after apicoectomy and resection of retained teeth
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

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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FDA 510(k) Summary

Date Prepared: August 16, 2023

Submitter's Contact Information

Submitter: SigmaGraft, Inc.
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Prepared By: Elcin Chang, General Manager

Email: e.chang@sigmagraft.com

Name of the Device

Trade Names:	InterCollagen® Guide
Common Name:	Bone Grafting Material
Classification Name:	Barrier, Animal Source, Intraoral
Regulation Number:	§872.3930
Device Classification:	II
Product Code(s):	NPL
Classification Panel:	Dental

Predicate Device

Primary Predicate:	Straumann Jason Membrane (K173562)
Common Name:	Bone Grafting Material
Classification Name:	Barrier, Animal Source, Intraoral
Regulation Number:	§872.3930
Device Classification:	II
Product Code(s):	NPL
Classification Panel:	Dental

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Device Description

InterCollagen® Guide is a resorbable collagen membrane, derived from porcine pericardium. InterCollagen® Guide is intended for periodontal and/or dental surgical procedures as a barrier membrane restricting the entry of rapidly proliferating non-osteogenic cells within the bone defect while allowing the ingrowth of slow-growing bone forming cells. The membrane is a bio-resorbable barrier which eventually is remodeled and/or incorporated by the host tissue. InterCollagen® Guide is substantially resorbed within 15 weeks after implantation. It is adaptable and easy to handle. It can be trimmed to the desired size and conforms easily when hydrated. The product is terminally sterilized via gamma irradiation.

Sizes

InterCollagen® Guide is provided in five different sizes:

Type	Size (mm)	Product code
Resorbable Collagen Membrane	12 x 25	ICG1225
	15 x 20	ICG1520
	20 x 30	ICG2030
	25 x 25	ICG2525
	30 x 40	ICG3040

Indications for Use

InterCollagen® Guide alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) can be used in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures as a biodegradable barrier for:

- in the context of a treatment of fenestration defects
- in case of dehiscence defects
- after apicoectomy and resection of retained teeth
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

Summary/Comparison of Technical Characteristics

The subject device has substantially equivalent technological characteristics to the marketed predicate device. A comparison of the relevant technological characteristics between the subject and primary predicate device is provided in the table that follows.

Biocompatibility Testing

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess the safety of the subject device. Testing was determined in accordance with ISO 10993-1 and FDA Guidance on

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Use of International Standard ISO 10993-1 for the biological evaluation of medical devices within a risk management process.

The biocompatibility testing performed is summarized in the table below.

Test	Standards	Result
Mouse Lymphoma forward mutation assay	ISO 10993-3, OECD 476, OECD 490	Non-mutagenic
Genotoxicity (Ames: Bacterial Reverse Mutation) Test	ISO 10993-3	Non-mutagenic
Kligman Maximization Sensitization Test	ISO 10993-10	Non-sensitizer
Intracutaneous irritation test	ISO 10993-10	Non-irritant
Cytotoxicity L929 Neutral Red uptake test	ISO 10993-5	Non-cytotoxic
Acute Systemic Toxicity Test	ISO 10993-11	Non-toxic
90 day Subchronic Toxicity Test	ISO 10993-11	Non-toxic
Pyrogenicity (material mediated)	ISO 10993-11	Non-pyrogenic
Local effects after Implantation Test	ISO 10993-6	Minimum tissue reaction at 2, 11, and 15 weeks of implantation and no adverse tissue reaction to the host

Animal Testing

The performance of the device in a canine two-wall intrabony defect model was compared to the performance of the predicate device, Jason membrane. The objective of this study was to evaluate the in vivo performance, local effects following implantation, and systemic toxicity of the test article, InterCollagen® Guide, in comparison to a predicate and empty control.

End points for pathology, histology, histomorphology and micro-CT were taken after 2, 6, and 13 weeks. The subject device performed in a manner substantially equivalent to the cleared predicate device.

Animal Tissue Management

Animal tissues are managed in accordance with the following standards and guidance documents:

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- ISO 22442-1 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1: Analysis and Risk Management*
- ISO 22442-2 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2: Controls on Sourcing, Collection, and Handling*
- ISO 22442-3 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3: Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents*
- Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) Guidance for Industry and Food and Drug Administration Staff, CDRH, FDA, March 15, 2019
- FDA Guidance for Industry – Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin, CDER, CBER, September 1998

Sterilization

Sterilization validation was performed in accordance with ISO 11137-1 *Sterilization of health care products – Radiation Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices,* ISO 11137-2 *Sterilization of health care products – Radiation Part 2 Establishing the sterilization dose, and* ISO 11737 *Sterilization of Medical Devices – Microbiological Method – Determination of the Population of Microorganisms on Products.*

Pyrogenicity

This device is non-pyrogenic. Each batch of product manufactured is tested for endotoxin per the Limulus Amebocyte Lysate (LAL) endotoxin test, USP <85> and USP <161>, as finished product release test.

Shelf Life and Stability

Product and packaging stability was determined using real-time aging data. Performance testing of packaging system was tested in accordance with ASTM D4169 *Standard Practice for Performance Testing of Shipping Containers and Systems*. Selection, qualification, and validation of packaging were conducted in accordance with ISO 11607 *Packaging for Terminally Sterilized Medical Devices – Requirements for Materials, Sterile Barrier Systems, and Packaging Systems*.

Viral Inactivation

Viral inactivation studies were performed in accordance with ISO 22442-3 to ensure the viral safety of the product.

Clinical Studies

Clinical performance data was not required to determine substantial equivalence.

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Conclusion

Chemical, physical, and biocompatibility tests as well as pre-clinical data show that the subject device is substantially equivalent to the predicate device. Comparison with the predicate device shows that the device has similar specifications and performance. Therefore, the conclusions drawn from the nonclinical and preclinical tests demonstrate that the device is substantially equivalent to its predicate device.

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Feature	InterCollagen® Guide (K223912) Test article	Straumann Jason Membrane (K173562) Predicate device	Equivalence Discussion
Indications for Use	InterCollagen® Guide alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) can be used in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures as a biodegradable barrier for: • in the context of a treatment of fenestration defects • in case of dehiscence defects • after apicoectomy and resection of retained teeth • in extraction sockets after tooth extractions • in case of immediate or delayed augmentation around implants in extraction sockets	Jason membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration. • In case of surgical bone defects and bone wall defects • In the context of sinus floor augmentation and support of the Schneiderian membrane • In the context of Maxillary ridge augmentation • In the context of Maxillary ridge reconstruction for prosthetic • In the context of Treatment Fenestration defects • In case of Periodontal bone defects (1-3 wall defects) and furcation defects (class I and II) • In case of Dehiscence defects after apicectomy, cystectomy, resection of retained teeth and resection of other bone lesions	**Equivalent** Both devices are indicated for immediate or delayed guided tissue and bone regeneration. The indications for the subject device are a subset of the indications for the predicate device.

		• In extraction sockets after tooth extractions • In case of immediate or delayed augmentation around implants in extraction sockets	
Mode of Action	InterCollagen® Guide is a bio-resorbable barrier which eventually is remodeled and/or incorporated by the host tissue.	Jason Membrane is a bio-resorbable barrier which eventually is remodeled and/or incorporated by the host tissue.	**Equivalent** Both devices are resorbable and function as a barrier to provide adequate new bone formation without soft tissue infiltration.
Operating Principle	Cell-occlusive Implantable Resorbable Biocompatible	Cell-occlusive Implantable Resorbable Biocompatible	**Equivalent** Both devices function as a barrier to provide adequate new bone formation without soft tissue infiltration. They are both implantable, resorbable, and biocompatible.
Material origin	Porcine pericardium	Porcine pericardium	**Equivalent** Both devices use a native collagen membrane obtained from porcine pericardium.
Collagen Type	Collagen Type I and Type III	Collagen Type I	**Equivalent** Both devices have mainly Collagen Type I.

Form	Membrane	Membrane	**Equivalent** They act as a barrier against the infiltration of cells not involved in bone formation.
Color	White to off white	White to off white	**Equivalent** Both devices have color that is white to off white.
Sizes	12 x 25 mm 15 x 20 mm 20 x 30 mm 25 x 25 mm 30 x 40 mm	15 x 20 mm 20 x 30 mm 30 x 40 mm	**Equivalent** Both devices are provided in clinically relevant sizes for intra-oral surgical procedures.
Resorption Time	Substantially resorbed by 15 weeks	Substantially resorbed by 12 weeks	**Equivalent** The longer endurance of the desired barrier properties provides adequate new bone formation without soft tissue infiltration.
Sterilization Method	Irradiation	Ethylene Oxide	**Equivalent** Both the subject and predicate device achieve a Sterility Assurance Level of 10^{-6}.
Single Use/Reuse	Single use only	Single use only	**Equivalent** Both devices are single use only.
Packaging	Double blister pack	Double pouch pack	**Equivalent** Both devices facilitate aseptic delivery of the sterile device into the sterile surgical field.