Institut Straumann AG
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

July 9, 2018

Re: K173562
Trade/Device Name: Straumann Jason Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: June 7, 2018
Received: June 8, 2018

Dear Jennifer Jackson:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K173562

Device Name

Straumann® Jason® Membrane

Indications for Use *(Describe)*

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 for support of the Schneiderian membrane
- in the context of maxillary ridge augmentation
- in the context of maxillary ridge reconstruction for prosthetic treatment
- in the context of a treatment of fenestration defects
- in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects)
- in case of dehiscence defects
- after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- 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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5. 510(k) Summary K173562

Submitter:
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Date Prepared: July 6, 2018

Product Code(s): NPL (21 CFR 872.3930)

Device Class: II (21 CFR 872.3930)

Classification Panel: Dental

Classification Name: Bone grafting material (21 CFR 872.3930)

Common Name Barrier, animal source, intraoral

Proprietary Name: Straumann® Jason® Membrane

Predicate Device(s): K141177, Vitala® Porcine Derived Collagen Membrane (Osteogenics Biomedical)

Reference Device(s): K050446, BIO-GIDE® (Geistlich)

Device Description: Jason® Membrane is a completely resorbable collagen membrane used in maxillofacial surgery, implantology, periodontology, oral surgery and endodontology as a barrier membrane to support guided tissue regeneration (GTR) and guided bone regeneration (GBR), for covering implants and for periodontal tissue regeneration. Jason membrane is produced from porcine pericardium in a standardized, controlled purification process. When dry Jason Membrane is a white collagen matrix with a very dense fiber structure. It possesses sufficient rigidity and stability for a broad variety of intended uses. Jason Membrane possesses a physiological neutral pH-

value. Jason Membrane typically resorbs within 12 weeks after implantation.

Jason Membrane is offered in three sizes as shown below.

Article No.	*Size*	*Content*
BS-681520	15 × 20 mm	1 membrane
BS-682030	20 × 30 mm	1 membrane
BS-683040	30 × 40 mm	1 membrane

Picture of Device

Indications For Use: 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 for support of the Schneiderian membrane
- in the context of maxillary ridge augmentation
- in the context of maxillary ridge reconstruction for prosthetic treatment
- in the context of a treatment of fenestration defects
- in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects)
- in case of dehiscence defects
- after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

Materials:

Jason Membrane is manufactured from the pericardium of domestic swine. The chemical content of 10 cm^2 Jason Membrane is:

- 30 - 40 mg collagen type I
- 5 - 10 mg purified water
- Up to 10% salts as sodium phosphate

Technological Characteristics:

A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Performance Data:

- Validation of Primary and Secondary barrier packaging per ISO 11607-2
- Validation of transport packaging per ASTM D4169
- Validation of sterilization parameters per ISO 11135
- Biocompatibility per ISO 10993-1 and the following:
  - 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 Ph.Eur.
- Viral Inactivation per ISO 22442-3
- Validation of shelf life per ASTM F1980 using age accelerated and real-time aged samples
- Physicochemical Characterization per ASTM F2212
- Tensile strength testing
- Suture pull-out strength testing
- Straumann sponsored animal study assessing soft tissue infiltration and membrane resorption kinetics of the subject device in an intra-oral critical size defect GBR model

Conclusions:

Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.

Feature	SUBJECT Device Straumann Jason Membrane	Primary PREDICATE Device Vitala Porcine Collagen Membrane (K141177)	Equivalence Discussion
Indications for Use	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 for support of the Schneiderian membrane • in the context of maxillary ridge augmentation • in the context of maxillary ridge reconstruction for prosthetic treatment • in the context of a treatment of fenestration defects • in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects) • in case of dehiscence defects • after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions • in extraction sockets after tooth extractions • in case of immediate or delayed augmentation around implants in extraction sockets	Vitala Porcine Derived Collagen Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: • Simultaneous use with 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; • Alveolar ridge preservation consequent to tooth extraction; • Filling of bone defects after root resection, cystectomy, or removal of retained teeth; • Over the window in lateral window sinus elevation procedures; • Furcation defects in multi-rooted teeth; • Treatment of recession defects, together with a coronally positioned flap; • In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection; • GBR of dehiscence defects; and • GTR in periodontal defects.	**Equivalent** The indications for the subject device are a subset of the indications for the predicate device.

Feature	SUBJECT Device Straumann Jason Membrane	Primary PREDICATE Device Vitala Porcine Collagen Membrane (K141177)	Equivalence Discussion
Mode of Action	Jason 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.	Vitala 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	Intact purified collagen tissue	Intact purified collagen tissue	**Identical**
Collagen Source	Porcine pericardium	Porcine pericardium	**Identical**
Form	Membrane	Membrane	**Identical**
Color	White to off-white	White to off-white	**Identical**
Sizes	Variety of sizes	Variety of sizes	**Equivalent** Both devices are provided in clinically relevant sizes for intra-oral surgical procedures
Resorption Time	Substantially resorbed by 12 Weeks	Substantially resorbed by 26 Weeks	**Equivalent** While the subject device resorbs more quickly than the primary predicate, the endurance of the desired barrier properties is sufficient to assure adequate new borne formation without soft tissue infiltration.
Sterilization Method	Ethylene Oxide	Irradiation	**Equivalent** Both the subject and predicate devices achieve a Sterility Assurance Level of 10^{-6}.
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	**Identical**

Feature	SUBJECT Device Straumann Jason Membrane	Primary PREDICATE Device Vitala Porcine Collagen Membrane (K141177)	Equivalence Discussion
Singe Use/ Reuse	Single use only	Single use only	**Identical**
Packaging	Double pouch pack	Double blister pack	**Equivalent** 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.