Datum Dental Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LPP
1735 Market Street
Floor 23
Philladelphia, Pennsylvania 19103

7/18/2022

Re: K212509
Trade/Device Name: OSSIX® Breeze
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: June 23, 2022
Received: June 23, 2022

Dear Janice Hogan:

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 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: 06/20/2023
See PRA Statement below

510(k) Number *(if known)*

K212509

Device Name

OSSIX® Breeze

Indications for Use *(Describe)*

OSSIX® Breeze membrane alone or in combination with suitable augmentation materials (like autologous bone or other bone replacement materials) is indicated for immediate or delayed guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable membrane for:

1) Alveolar ridge augmentation and reconstruction,
2) Alveolar ridge preservation consequent to tooth extractions,
3) Over the window in sinus elevation procedures and for support of the Schneiderian membrane,
4) In intra bony defects around teeth,
5) Guided tissue regeneration procedures in 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
Datum Dental Ltd.'s OSSIX® Breeze
K212509

I. 510(k) Applicant

Datum Dental Ltd.
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Lod 7120101 Israel
Phone: 1-972-8-6705400
Fax: 1-972-8-6705429

Contact person: Lyudmila Kipnis, Director of Regulatory Affairs
Date prepared: July 18, 2022

II. Device

Trade name: OSSIX® Breeze
Common name: Cross-Linked Pericardium Membrane
Classification name: Barrier, animal source, intraoral (21 CFR 872.3930)
Regulatory class: II
Product code: NPL

III. Predicate Device

Primary predicate: OSSIX® Plus (K160281)
Reference device: Straumann® Jason® Membrane (K173562)

IV. Device Description

OSSIX® Breeze cross-linked pericardium membrane is a biodegradable and biocompatible collagen membrane intended for guided tissue and bone regeneration. The membrane is manufactured from decellularized pericardia of pigs that are veterinary certified as fit for human consumption and is cross-linked using ribose.

OSSIX® Breeze is packed in a double blister and an outer paperboard box and is sterilized by ethylene oxide.

Due to its porous and fibered microstructure, the membrane readily adheres to the surrounding tissues and provides a barrier that guides bone and tissue regeneration.

Available in sizes: 10x12 mm, 15x20 mm, 20x30 mm and 30x40 mm.

OSSIX® Breeze is intended for use in adults and should only be used by trained dentists or oral surgeons.

V. Indications for Use

OSSIX® Breeze membrane alone or in combination with suitable augmentation materials (like autologous bone or other bone replacement materials) is indicated for immediate or delayed guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable membrane for:

1) Alveolar ridge augmentation and reconstruction,
2) Alveolar ridge preservation consequent to tooth extractions,
3) Over the window in sinus elevation procedures and for support of the Schneiderian membrane,
4) In intra bony defects around teeth,
5) Guided tissue regeneration procedures in periodontal defects.

VI. Comparison of Technological Characteristics with the Predicate Device

OSSIX® Breeze has similar technological characteristics as the predicate device OSSIX® Plus. Both devices are manufactured from porcine collagen that is subjected to identical cross-linking process to provide the product with better resistance to degradation. Both products are highly porous three-dimensional conductive membranes structured with a lattice network of fibrillated cross-linked collagen with a pore size that is occlusive for epithelial gingival cells. The dimensions of both products are comparable, with thickness (dry membrane) of about 0.2 mm for OSSIX® Plus and 0.1-0.2 mm for OSSIX® Breeze, and up to 30x40 mm in the length and width of both devices.

The principal difference between OSSIX® Breeze and OSSIX® Plus is that OSSIX® Plus is manufactured by reconstitution of soluble purified type I collagen derived from porcine tendons, while OSSIX® Breeze is produced from insoluble collagen of decellularized porcine pericardia. In both products, the collagen is subject to similar viral inactivation (alkaline treatment), cross-linking (glycation based), and sterilization (ethylene oxide) methods. Comparative nonclinical testing between the subject OSSIX® Breeze and predicate OSSIX® Plus demonstrates that the devices have comparable physicochemical and biochemical characteristics except for minor differences in porosity, water-uptake, microstructure and mechanical properties. Additional bench testing that compared the subject device OSSIX® Breeze to the reference device

Straumann® Jason® membrane, which is also manufactured from acellularized porcine pericardium, demonstrated that both products are comparable in terms of these characteristics.

Regarding principles of operation, the subject device as well as the predicate and reference devices are applied and work in the same manner by adhering to the surrounding tissues and providing a barrier that guides bone and tissue regeneration.

Therefore, both the subject OSSIX® Breeze and the predicate OSSIX® Plus have the same intended use and similar indications for use, composition, structure, manufacturing process, and physicochemical characteristics. The minor technological differences between OSSIX® Breeze and its predicate devices raise no new issues of substantial equivalence. Performance data demonstrate that OSSIX® Breeze is substantially equivalent to OSSIX® Plus.

A comparison chart of OSSIX® Breeze with the predicate and reference devices is provided below:

	Subject device	**OSSIX® Plus (K160281)**	**Straumann® Jason® Membrane (K173562)**
Intended use/ Indications for use	OSSIX® Breeze membrane alone or in combination with suitable augmentation materials (like autologous bone or other bone replacement materials) is indicated for immediate or delayed guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable membrane for: 1) Alveolar ridge augmentation and reconstruction, 2) Alveolar ridge preservation consequent to tooth extractions, 3) Over the window in sinus elevation procedures and for support of the	OSSIX® Plus biodegradable collagen membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: • Ridge augmentation for later implant insertions. • Simultaneous ridge augmentation and implant insertions. • Ridge augmentation around implants inserted in delayed extraction sites. • Ridge augmentation around implants inserted in immediate extraction sites. • Alveolar ridge preservation consequent to tooth (teeth) extraction(s). • Over the window in lateral window sinus	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

	Subject device	OSSIX® Plus (K160281)	Straumann® Jason® Membrane (K173562)
	Schneiderian membrane, 4) In intra bony defects around teeth, 5) Guided tissue regeneration procedures in periodontal defects.	elevation procedure. • In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved. • In intra bony defects around teeth. • For treatment of recession defects, together with coronally positioned flap. • In furcation defects in multi rooted teeth.	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
Mode of Action	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.	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.	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.
Operating Principles	• Cell-occlusive • Implantable • Resorbable • Biocompatible	• Cell-occlusive • Implantable • Resorbable • Biocompatible	• Cell-occlusive • Implantable • Resorbable • Biocompatible
Material	Porcine decellularized pericardia	Porcine tendons	Porcine decellularized pericardia
Collagen Source	Porcine pericardium	Porcine tendons	Porcine pericardium
Technology	Cross-linked (ribose) decellularized pericardium	Cross-linked (ribose) reconstituted purified collagen	Non-cross-linked decellularized pericardium
Form	Membrane	Membrane	Membrane
Color	White to off-white	White to off-white	White to off-white
Sizes	• 10x12mm • 15x20mm • 20x30mm • 30x40mm	• 10x12.5mm • 15x25mm • 25x30mm • 30x40mm	• 15x20mm • 20x30mm • 30x40mm

	Subject device	OSSIX® Plus (K160281)	Straumann® Jason® Membrane (K173562)
Resorption Time	Substantially resorbed by 24 weeks	Substantially resorbed by 24 weeks	Substantially resorbed by 12 weeks
Single use	Yes	Yes	Yes
Packaging	Double blister pack. Two layers of sterile barrier packaging to facilitate the aseptic delivery of the sterile device into the sterile surgical field.	Double blister pack. Two layers of sterile barrier packaging to facilitate the aseptic delivery of the sterile device into the sterile surgical field.	Double pouch pack. Two layers of sterile barrier packaging to facilitate the aseptic delivery of the sterile device into the sterile surgical field.
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}

VII. Summary of Data to Support Substantial Equivalence

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, and biocompatibility testing of the subject device.

Non-clinical biocompatibility testing was performed in accordance with the following FDA recognized consensus standards:

- ISO 10993-1:2018 Biological evaluation of medical devices- Part 1 - Evaluation and testing within a risk management process
- ISO 10993-2:2006 Biological Evaluation of medical devices - Part 2: Animal welfare requirements
- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO/TR10993-33:2015 Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 /AC:2009 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residues
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices-Part 11-Tests for systemic toxicity

- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

The control of animal materials is performed following:

- ISO 22442-1:2020 - Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
- ISO 22442-2:2020 - Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling
- ISO 22442-3:2007 - Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) Agents.

The sterilization process is established and performed according to:

- ISO 11135:2014 - Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

A series of bench tests were conducted to evaluate the biochemical and physicochemical properties of the device. *In vitro* product characterization testing was performed comparing the subject device to the predicate as well as to the reference devices demonstrating substantial equivalence. Specifically, the bench testing includes the following categories:

- Weight and dimensions (weight, size, thickness, expansion upon hydration and water uptake),
- Composition and purity (carbohydrates, heavy metals, endotoxins, ethanol, EtO residues, organic extractables, DNA, moisture, total organic content, minerals, amino acids and pH),
- Enzymatic (collagenase and trypsin digestion),
- Structural (SEM analysis, porosity, density, denaturing temperature, integrity upon wetting, solubility, and FT-IR spectroscopy),
- Mechanical properties (maximum load/tensile strength, suture retention, fixability).

An *in vivo* animal study was conducted in a beagle mandibular guided bone regeneration model to evaluate the *in vivo* performance, degradation and safety of OSSIX® Breeze dental membrane as compared to the predicate membrane, OSSIX® Plus. The subject device performed in a manner substantially equivalent to the cleared predicate membrane, OSSIX® Plus. The study design included defects of 10 ± 1 mm mesiodistally (z-distance), 8 ± 1 mm occlusal-apically (y-distance), and 7 ± 1 mm buccolingually (x-distance). Each defect was either left untreated

(negative control) or implanted with the bone grafting material OSSIX Bone and covered with the assigned membrane either OSSIX Breeze (subject device) or OSSIX Plus (predicate device). End points for pathology, histology, histomorphology and micro-CT were taken after 4, 12 and 24 weeks. The subject device performed in a manner substantially equivalent to the cleared predicate device.

VIII. Conclusion

Based on the data provided within these 510(k) submissions as summarized above, it is concluded that OSSIX® Breeze is substantially equivalent to the predicate device.