Datum Dental, Ltd.
% Kelliann Payne
Partner
Hogan Lovells US Llp
1735 Market St., Floor 23
Philadelphia, Pennsylvania 19103

October 29, 2026

Re: K262415
Trade/Device Name: OSSIX Plus
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: July 15, 2026
Received: July 31, 2026

Dear Kelliann Payne:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262415

Device Name
OSSIX® Plus

Indications for Use (Describe)

OSSIX® Plus is a resorbable collagen membrane 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 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.

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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510(k) SUMMARY

OSSIX® Plus

K262415

Submitter:

Datum Dental Ltd.
38 Hayarkon St., Yavne,
Israel 8122741

Submission Correspondent:

Kelliann Payne
Hogan Lovells Cadwalader US LLP
kelliann.payne@hlc.com
(267) 675-4687

Date Prepared: October 29, 2026

Name of Device:

OSSIX® Plus

Classification Name:

21 CFR 872.3930 (Bone grafting material)
Class II
Product Code NPL - Barrier, Animal Source, Intraoral

Predicate Device

OSSIX® Plus (K160281)

Reference Devices

None

Device Description

OSSIX® Plus is a biodegradable and biocompatible collagen membrane intended for use during the process of guided tissue and bone regeneration. The collagen is derived from tendons of veterinary-certified pigs and is purified and cross-linked using ribose. OSSIX® Plus is packaged in a double blister and an outer cardboard box and is sterilized by ethylene oxide. Due to its porous and fibrous microstructure, the membrane readily absorbs fluids, adheres to the surrounding tissues and provides a barrier that guides bone and tissue regeneration. Available in sizes: 15x25 mm, 25x30 mm, and 30x40 mm. Intended for use by dental surgeons.

Intended Use / Indications for Use

OSSIX® Plus is a resorbable collagen membrane 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 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.

Comparison of Technological Characteristics with the Predicate Device

OSSIX® Plus is a resorbable collagen membrane intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier. The subject device has the same intended use and identical indications for use as the predicate OSSIX® Plus device previously cleared under K160281. This submission supports the transfer of manufacturing facility, and does not reflect a change to the device's intended use, indications for use, design, raw materials, composition, primary barrier system, sterilization modality, or fundamental principles of operation. In addition, several minor manufacturing-related changes, including updates to in-process testing methods, suppliers, equipment, and secondary packaging configurations, were implemented under the company's quality system and validated as appropriate, with no adverse impact on device design, intended use, product quality, safety, or performance.

Characteristic	Subject Device	Predicate Device	Assessment
	OSSIX® Plus	**OSSIX® Plus (K160281)**	
Intended use / Indications for use	OSSIX® Plus is a resorbable collagen membrane 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.	OSSIX® Plus is a resorbable collagen membrane 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;	Identical

Characteristic	Subject Device	Predicate Device	Assessment
	OSSIX® Plus	**OSSIX® Plus (K160281)**	
	– 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 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.	– 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 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.	
Contraindications	OSSIX® Plus must not be used in: 1. Patients with known collagen hypersensitivity. 2. Patients with sensitivity to porcine-derived materials.	OSSIX® Plus must not be used in: 1. Patients with known collagen hypersensitivity. 2. Patients with sensitivity to porcine-derived materials.	Substantially equivalent; additional contraindications added to align IFU with EU labeling requirements.

Characteristic	Subject Device	Predicate Device	Assessment
	OSSIX® Plus	**OSSIX® Plus (K160281)**	
	3. Patients suffering from autoimmune diseases and connective tissue diseases, such as: systemic lupus erythematosus, dermatomyositis, etc. 4. Patients with acute or chronic infection (osteomyelitis) at the surgical site. 5. In patients that have received or are currently receiving treatment with intravenously administered bisphosphonates.	3. Patients suffering from autoimmune diseases and connective tissue diseases, such as: systemic lupus erythematosus, dermatomyositis, etc.	
Composition of Materials	Cross-linked porcine type I collagen	Cross-linked porcine type I collagen	Identical
Usage	Single Use	Single Use	Identical
Classification name	Barrier, animal source, intraoral	Barrier, animal source, intraoral	Identical
Product Code	NPL	NPL	Identical
Class	21 CFR §872.3930, Class II	21 CFR §872.3930, Class II	Identical
Product Design	Resorbable dental membrane made of porous lattice network of collagen	Resorbable dental membrane made of porous lattice network of collagen	Identical
Properties	• Biocompatible; • non-pyrogenic; • non-antigenic; • porous and fibered microstructure; • readily absorbs bodily fluid; • adheres well to the surrounding and underlying tissues; • is not disrupted by closure of the surgical site;	• Biocompatible; • non-pyrogenic; • non-antigenic; • porous and fibered microstructure; • readily absorbs bodily fluid; • adheres well to the surrounding and underlying tissues; • is not disrupted by closure of the surgical site;	Substantially equivalent, as established through bench and biocompatibility testing.

Characteristic	Subject Device	Predicate Device	Assessment
	OSSIX® Plus	**OSSIX® Plus (K160281)**	
	• slowly resorbed and replaced by new tissue.	• slowly resorbed and replaced by new tissue.	
Dimensions	15x25 mm; 25x30 mm; 30x40 mm	15x25 mm; 25x30 mm; 30x40 mm	Identical
Thickness	About 0.2 mm	About 0.2 mm	Identical
Porosity	About 86%	About 80%	Substantially equivalent; porosity percentage remained comparable and average pore diameter remained within the same sub-micrometer range for cell occlusion and barrier function.
Wettability	Wettable and completely soaked in aqueous solution in less than one minute	Wettable and completely soaked in aqueous solution in less than one minute	Identical
Cross-linking	Chemically cross-linked with ribose	Chemically cross-linked with ribose	Identical
Trimmable	Trimmable with surgical instruments	Trimmable with surgical instruments	Identical
Source	Porcine tendons	Porcine tendons	Identical
Fat (Lipids)	<0.1%	<0.1%	Identical
Purified Collagen Intermediate	PUC	PUC	Identical
pH	6-8	6-8	Identical
Packaging	Double blisters system	Double blisters system	Substantially equivalent. Primary barrier system unchanged. Minor modifications to secondary shipping configurations, including transition from the historical 10-box configuration to validated 100-unit and 200-unit master shipper

Characteristic	Subject Device	Predicate Device	Assessment
	OSSIX® Plus	OSSIX® Plus (K160281)	
			configurations, do not affect product performance or package integrity.
Sterilization	Ethylene oxide	Ethylene oxide	Identical
Sterility	SAL 10^{-6}	SAL 10^{-6}	Identical

Therefore, OSSIX® Plus manufactured at the Yavne facility has the same intended use and indications for use, and similar technological characteristics as the predicate OSSIX® Plus device previously cleared under K160281.

Summary of Data to Support Substantial Equivalence

Datum Dental conducted a comparability program assessing whether OSSIX® Plus manufactured at the new facility continues to meet established specifications and maintains the same safety and performance profile as product manufactured at the old facility. The evidence includes specification testing, physicochemical characterization, biocompatibility testing, and viral safety support.

Bench Testing

Datum Dental conducted bench testing to support the site transfer and demonstrate that the OSSIX® Plus device manufactured in the new facility is equivalent to the previously cleared OSSIX® Plus. This bench testing included the following categories:

Specification testing:

- Appearance
- Weight
- Heavy metal content (USP <233>)
- Collagenase resistance and trypsin resistance
- Endotoxins (ANSI AAMI ST72:2019; USP <85>)

Physicochemical characterization:

- Dimensional checks
- Water uptake
- Denaturation temperature (USP <891>)
- Ethanol residuals
- Tensile strength
- Porosity
- Thermogravimetric Analysis (TGA)
- Surface morphology

Biocompatibility Testing

OSSIX® Plus was subjected to biocompatibility studies according to ISO 10993-1, including:

- Cytotoxicity (ISO 10993-5);
- Rabbit pyrogenicity (ISO 10993-11; USP <151>);
- Sensitization (ISO 10993-10);
- Intracutaneous reactivity (ISO 10993-23);
- Acute systemic toxicity (ISO 10993-11);
- Genotoxicity (ISO 10993-3); and
- Ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals (ISO 10993-7).

These results, together with historical biocompatibility data previously provided in K053260 and K160281, supported the conclusion that the transferred process does not introduce new or increased biological risk and that the subject device can be considered biocompatible for use as intended.

Viral Safety

Viral safety is supported through controlled porcine tissue sourcing and viral inactivation and clearance studies for the predicate device, previously provided in K053260 and K160281. OSSIX® Plus continues to meet the predefined viral safety acceptance criteria. Risk management, animal sourcing and collection, and process validation were conducted in accordance with ISO 22442 Parts 1, 2, and 3, respectively.

Packaging Validation

Packaging validation testing demonstrated that the updated secondary packaging configurations maintain package integrity, sterile barrier performance, and product protection under simulated shipping conditions. Shipping simulation was performed per ASTM D4169 (Distribution Cycle 13) and ASTM F2825, followed by sterile barrier integrity and seal strength testing per ASTM F1929 (dye penetration), ASTM F2096 (bubble leak), and ASTM F88 (seal strength).

Shelf Life

The 36-month shelf life was previously established on real-time stability data (K160281). Product stability comparability testing and packaging stability testing in accordance with ISO 11607-1 and ISO 11607-2, confirm that the labeled 36-month shelf life remains applicable to the subject device.

Sterilization Validation

The post-sterilization aeration conditions were modified while maintaining the existing EO sterilization method previously validated in K160281. Validation testing per ISO 11135 demonstrated that the revised process maintains a sterility assurance level (SAL) of 10^{-6} and EO and ECH residuals met the limits of ISO 10993-7, supporting the continued safety and performance of the device.

Animal Testing

No new animal testing was conducted; the in vivo performance previously established for OSSIX® Plus (K053260, K160281) remains applicable, as the subject changes are limited to the manufacturing site and associated processes and were addressed through comparative nonclinical testing.

Conclusion

The information provided in this submission demonstrates that the subject OSSIX® Plus has the same indications for use and similar technological characteristics as the predicate OSSIX® Plus device. The manufacturing facility transfer and other minor manufacturing changes do not raise new questions of safety or effectiveness, and performance testing demonstrates that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to OSSIX® Plus (K160281).