August 16, 2024

Collagen Solutions, LLC
% Richelle Helman
Senior Director, Regulatory
MEDIcept Inc.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K240133
Trade/Device Name: Xenograft Bovine Bone Particulate
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: January 16, 2024
Received: July 22, 2024

Dear Richelle Helman:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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 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)*
K240133

Device Name
Xenograft Bovine Bone Particulate

Indications for Use *(Describe)*
Xenograft Bovine Bone Particulate is intended for use in dental surgery.
The products may be used in surgical procedures such as:
* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of defects in conjunction with products intended for Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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.

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

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Date:	15-August-2024
Company:	Collagen Solutions 6455 City West Pkwy Eden Prairie, MN 55344 Phone: (320) 510-3615
Applicant Contact:	Sheila Hunter Vice President of Quality and Regulatory Affairs
Official Contact:	Richelle Helman Senior Director, Regulatory
Proprietary or Trade Name:	Xenograft Bovine Bone Particulate
Common/Usual Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material, Animal Source
Regulation Number:	21 CFR 872.3930 Classification Product Code: NPM
Predicate Device:	K043034: Collagen Matrix OsteoGuide™ Anorganic Bone Mineral

Device Description:
The Xenograft Bovine Bone Particulate is a porous bone mineral matrix that is used in periodontal, oral, and maxillofacial surgery. It has a trabecular architecture, interconnecting macro and micro pores and consistency which allows formation and ingrowth of new bone. The particulate is available in clinically relevant sizes. The anorganic bone composition meets all requirements found in ASTM 1581-08: Standard Specification for Composition of Anorganic Bone for Surgical Implants. The device is packaged, labeled, and electron beam irradiated to meet all requirements and is non-pyrogenic. Using standard dental techniques, the dentist will loosely pack the xenograft particulate granules into the osseous defect using sterile instruments.

Indications for Use:
Xenograft Bovine Bone Particulate is intended for use in dental surgery.
The products may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of alveolar ridge
- Filling of periodontal defects
- Filling of defects after root resection, apicocectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Substantial Equivalence:
The Collagen Solutions Xenograft Bovine Bone Particulate is substantially equivalent to the predicate device, the Collagen Matrix OsteoGuide™ Anorganic Bone Mineral (510(k) K043034). The table below presents the similarities and differences between the products for substantial equivalence purposes. The difference between the subject device and the predicate device does not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Characteristic	**Subject Device:** Collagen Solutions Xenograft Bovine Bone Particulate	**Predicate Device:** Collagen Matrix, Inc. OsteoGuide Anorganic Bone Mineral [510(k) K043034]	**Substantial Equivalence**
Indications for Use	Xenograft Bovine Bone Particulate is intended for use in dental surgery. The products may be used in surgical procedures such as: * Augmentation or reconstructive treatment of alveolar ridge * Filling of periodontal defects * Filling of defects after root resection, apicocectomy, and cystectomy * Filling of extraction sockets to enhance preservation of the alveolar ridge * Elevation of maxillary sinus floor * Filling of periodontal defects in conjunction with products intended for Guided Bone Regeneration (GBR) * Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)	Natural Anorganic Bone Graft Substitutes are intended for use in dental surgery. The products may be used in surgical procedures such as: * Augmentation or reconstructive treatment of alveolar ridge * Filling of periodontal defects * Filling of defects after root resection, apicocectomy, and cystectomy * Filling of extraction sockets to enhance preservation of the alveolar ridge * Elevation of maxillary sinus floor * Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR) * Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration	**SAME**
Physical Form	Ground bone particulate in a dappen dish	Ground bone particulate in a dappen dish	**SAME**
Color	White to off-white	White to off-white	**SAME**
Material composition	Anorganic bovine bone mineral	Anorganic bovine bone mineral	**SAME**

Collagen Solutions (US) LLC
6455 City West Parkway
Eden Prairie, MN, USA 55344

Characteristic	Subject Device: Collagen Solutions Xenograft Bovine Bone Particulate	Predicate Device: Collagen Matrix, Inc. OsteoGuide Anorganic Bone Mineral [510(k) K043034]	Substantial Equivalence
Size (Dimension and weight)	Small Cancellous Granules (0.25-1mm): 0.25g/0.6cc, 0.5g/1.2cc, 1.0g/2.4 cc, *1.25g/3.0 cc*, 2.0 g/4.7 cc Large Cancellous (1-2 mm): 0.25g/0.85cc, 0.5g/1.7cc, 1.0g/3.4 cc, *1.2g/4.0 cc*, 2.0 g/6.8 cc Cortical Bone (0.5-1 mm): 0.25g/0.4 cc, 0.5g/0.8cc, 1.0g/1.6 cc, *1.25g/2.0 cc*, 2.0 g/3.2 cc	Small Cancellous Granules (0.25-1mm): 0.25g/0.6cc, 0.5g/1.2cc, 1.0g/2.4 cc, 2.0 g/4.7 cc Large Cancellous (1-2 mm): 0.25g/0.85cc; 0.5g/1.7cc, 1.0g/3.4 cc; 2.0 g/6.8 cc Cortical Bone (0.5-1 mm): 0.25g/0.4cc, 0.5g/0.8cc, 1.0g/1.6 cc, 2.0 g/3.2 cc	**SIMILAR** The subject device has one additional size in each bone type that is within the range of sizes available in the predicate device.
Source of bone	Bovine	Bovine	**SAME**
Physical morphology	Trabecular, interconnected macro and micro pores	Trabecular, interconnected macro and micro pores	**SAME**
Crystallinity	83-98%	83-98%	**SAME**
Calcium Phosphate Ratio	2.3-2.5	2.3-2.5	**SAME**
Resorption Time	> 6 months	> 6 months	**SAME**
Performance	Bone formation	Bone formation	**SAME**
FDA Recognized Standards	ASTM F1581 ISO 10993-1	ASTM F1581 ISO 10993-1	**SAME**

From the comparison form above, the subject device and predicate device have the same intended use and the same operating principle for acting as a scaffold for new bone formation in dental surgery. The minor difference in the additional sizes offered does not raise different questions of safety or effectiveness.

Non-clinical performance testing:
Bench / Performance Testing –

- Bench testing was conducted in order to demonstrate that Collagen Solutions Xenograft Bovine Bone Particulates perform according to its requirements and specifications. In particular, the composition of the Collagen Solutions Xenograft Bovine Bone Particulates meets the requirements of ASTM F1581 “Standard Specification for Composition of Anorganic Bone for Surgical Implants”.
    - Apparent Density
    - Ca/P ratio

- Crystallinity
- Protein Content
- Heavy metal

- Biocompatibility was evaluated in accordance with ISO 10993-1 as follows:
  - Cytotoxicity per ISO 10993-5
  - Irritation per ISO 10093-10
  - Sensitization per ISO 10993-10
  - Genotoxicity per ISO 10993-3
  - Acute systemic toxicity per ISO 10993-11
  - Subchronic toxicity per ISO 10993-11
  - Implantation per ISO 10993-6
  - Pyrogenicity per ISO 10993-11 and endotoxin testing (LAL, Limulus Amebocyte Lysate) per USP <85>

  All tests indicated the patient contact materials were biocompatible.
- The product is radiation sterilized. Sterilization process validation was performed in accordance with the ANSI/AAMI/ISO 11137 series demonstrating a Sterility Assurance Level (SAL) of 10^{-6}.

The in-vivo performance of the subject device in a beagle mandibular intraoral critical size defect model was compared to that of the primary predicate device, Collagen Matrix OsteoGuide™ Anorganic Bone Mineral. New bone formation, presence of residual graft material and tissue reaction were assessed by histomorphometry and histopathology, at 4, 12 and 24 weeks for the subject device, primary predicate device and negative control. The results demonstrated that the performance of the subject and primary predicate devices was substantially equivalent.

The results demonstrated that the Collagen Solutions Xenograft Bovine Bone Particulates performs according to its specifications and functions as intended.

Substantial Equivalence Conclusion

Performance testing demonstrated that any risks associated with the subject device do not raise any new questions of substantial equivalence. The minor difference in sizes offered does not raise different questions of substantial equivalence based on the performance data. The use of the Collagen Solutions Xenograft Bovine Bone Particulates is substantially equivalent to the predicate device.