June 25, 2024

Bioventus LLC
Shanna Hu
Sr. Manager RA, FES Technology
4721 Emperor Blvd., Suite 100
Durham, North Carolina 27703

Re: K233368
Trade/Device Name: Allograft Delivery Device (OFAC-C)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: May 24, 2024
Received: May 24, 2024

Dear Shanna Hu:

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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.06.25 15:21:19 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

Submission Number *(if known)*

K233368

Device Name

Allograft Delivery Device (OFAC-C)

Indications for Use *(Describe)*

The Allograft Delivery Device is intended to be used for the delivery of hydrated allograft to an orthopedic surgical site.

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
Allograft Delivery Device

Submitter Information:

Company: Bioventus LLC
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Contact: Shanna Hu
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Date Prepared: June 24, 2024

Device Information:

Trade Name:	Allograft Delivery Device
Common Name:	Graft Delivery Device
Regulation Name:	Piston Syringe
Regulation Number:	21 CFR 880.5860
Regulatory Classification:	Class II
Product Code:	FMF
Proposed Panel:	General Hospital

Predicate Device:

Name:	Bi-Portal Bone Graft Delivery Device (KG™1 Graft Delivery Canula)
Manufacturer:	Spinal Surgical Strategies, LLC (Kleiner Device Labs)
510(k):	K142661

Device Description:

The Allograft Delivery Device is a sterile, single-use, disposable allograft delivery device intended for the delivery of hydrated allograft bone graft material to an orthopedic surgical site. The delivery device consists of a cannula used for containing and delivering the allograft material to the surgical site and a push rod required for expressing the allograft material from the cannula.

The cannula component is an open bore tube with a male double-threaded lock interface that mates with a pre-existing allograft syringe. The cannula component may be used to dispense allograft to a patient orthopedic surgical site. When used as an ancillary device to orthopedic surgical procedures that require the placement of allograft, the Allograft Delivery Device can deliver a prepared amount of allograft material.

Indications for Use:

The Allograft Delivery Device is intended to be used for the delivery of hydrated allograft to an orthopedic surgical site.

Substantial Equivalence:

The Allograft Delivery Device was evaluated to verify substantial equivalence. The indication for use of the subject device is the same as the predicate device. The comparison table provides an overview of the indications, key features, and technological comparison of the device to the predicate device. These comparisons support substantial equivalence for the intended use, technology, function, and mechanism of action to the predicate. The Allograft Delivery Device does not introduce any new issues of safety or efficacy relative to the predicate device.

Comparison Table:

Attributes	**Allograft Delivery Device (Subject Device)**	**Bi-Portal Bone Graft Delivery Device (Predicate Device)**
Applicant	Bioventus LLC	Spinal Surgical Strategies, LLC (Kleiner Device Labs)
Regulation No. & Name	21 CFR 880.5860, Piston Syringe	21 CFR 880.5860, Piston Syringe
Product Code	FMF	FMF
510(k) Number	K233368	K142661
Indications for Use	The Allograft Delivery Device is intended to be used for the delivery of hydrated allograft to an orthopedic surgical site.	The Bi-Portal Bone Graft Delivery Device is intended to be used for the delivery of hydrated allograft or autograft to an orthopedic surgical site.

Prescription / OTC Use	Prescription Use	Prescription Use
Type of Use	Single-Use, Disposable	Single-Use, Disposable
Mechanism of Operation	Graft dispersed from device tip by depressing syringe plunger and by the action of a push rod.	Graft dispersed from device tip by depressing plunger
Graft Injection	Single distal hole delivery into surgical space	Bilateral sidehole delivery into surgical space
Device Materials	Biocompatible Medical grade polypropylene	Biocompatible Medical Grade Plastics
Device Components	Cannula Barrel and Push Rod	Barrel, Plunger and Funnel
Bone Graft Exit Hole Diameter	Single distal hole 5.5 mm	Two sideholes: 5.6 mm x 14.8mm
Barrel Shape	Round, Curved	Rectangular, Straight
Volume Capacity	Up to 4.6 cc in Cannula Barrel	Up to 4.0 cc in Barrel
Sterility Claim / Sterility Assurance Level (SAL)	Sterile, SAL 1×10^{-6}	Sterile, SAL 1×10^{-6}
Sterilization Method	Gamma irradiation	Ethylene Oxide gas

Performance Data:

The following performance data were provided in support of the substantial equivalence determination:

Sterilization and Shelf-life

Sterilization validation was conducted to confirm that the subject device reached 10^{-6} sterility assurance level and the performance of the device and packaging are in line with expectations after sterilization requirements per ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3: 2017 standards. The sterilization process has been successfully validated and the sterility tests are within satisfactory limits.

The shelf-life validation study was conducted under the accelerated aging condition according to ASTM F1980-21 to verify the packaging integrity as well as the physical properties of the Allograft Delivery Device are within pass limits both before and after the aging process. The results successfully demonstrate an up to 1 year shelf life.

Sterile barrier testing was conducted in compliance with the following FDA-recognized consensus standards:

- Visual Inspection, F1886/F1886M-16
- Bubble Leak, ASTM F2096-11
- Seal Strength, ASTM F88/F88M-21

Biocompatibility Testing

The biocompatibility evaluation for the Allograft Delivery Device was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'" issued on September 8, 2023, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The following tests were conducted:

- Cytotoxicity
- Pyrogenicity
- Irritation
- Acute Systemic Toxicity
- Sensitization

All of the tests received passing results, demonstrating that the Allograft Delivery Device meets the applicable requirements outlined in the FDA guidance on ISO 10993-1.

Functional verification

- Cannula Buckling
- Plunger Force
- Cannula Connection Strength
- No gross separation of fluids from allograft
- Cannula Durability
- Push Rod Function/Strength

Shipping/Transit

Shipping/Transit testing was conducted as per ASTM D4169-22

Usability testing

Usability testing was conducted as per IEC 62366-1 edition 1.1 2020-06

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is substantially equivalent to the predicate device.

Conclusion:

The Allograft Delivery Device is substantially equivalent to the Bi-Portal Bone Graft Delivery Device in intended use, mechanism of operation, and patient-contacting materials. Performance testing has been conducted to demonstrate the subject device and predicate device technological characteristics are equivalent and that the subject device is as safe and as effective as the predicate device.