December 18, 2024

Ventris Medical
John Brunelle
Chief Operating Officer
1201 Dove Street, Suite 470
Newport Beach, California 92660

Re: K240765
Trade/Device Name: Porous Biologic Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: March 23, 2024
Received: November 4, 2024

Dear Mr. Brunelle:

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.

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 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,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2024.12.18 10:37:14 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K240765

Device Name

Porous Biologic Scaffold

Indications for Use *(Describe)*

Porous Biologic Scaffold is a bone void filler intended for use in bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created or a result of traumatic injury to the bone. Porous Biologic Scaffold is indicated to be packed gently into bony voids or gaps of the pelvis and posterolateral spine and is used combined with autograft as a bone graft extender. The device is resorbed and replaced with host bone during the healing process.

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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510(k) Summary

Submitter Information

Name:	Ventris Medical
Address:	1201 Dove Street, Suite 470 Newport Beach, CA 92660
Contact Person:	John Brunelle, PhD Chief Operating Officer
Telephone:	(949) 706-5551 (617) 448-6570
Date Prepared:	March 23, 2024

Device Information

Trade Name:	Porous Biologic Scaffold
Common Name:	Bone void filler/ Bone graft substitute
Classification:	Class 2
Regulation:	888.3045, Resorbable calcium salt bone void filler device
Product Code:	MQV, MBP

Predicate Device(s)

Primary Predicate (Intended Use):
1. K140375: Mastergraft Putty (Medtronic)

Reference Predicates:
2. K172130: Resorbable Mesh Device (Seaspine)
3. K122513: Magnifuse II (Medtronic)
4. K082002: Progenix Plus (Medtronic)
5. K100461: PGA Absorbable Surgical Suture (Riverpoint Medical)

Indications For Use

Porous Biologic Scaffold is a bone void filler intended for use in osseous defects of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created or the result of traumatic injury to the bone. Porous Biologic Scaffold is indicated to be packed gently into bony voids or gaps of the pelvis and posterolateral spine and is used combined with autograft as a bone graft extender. The device is resorbed and replaced with host bone during the healing process.

Device Description

Porous Biologic Scaffold is a resorbable bone void filler that is available in two versions:

Version 1 is comprised of a porous collagen mesh that is either prefilled or separately packaged with human demineralized allograft bone matrix. In the prefilled format, the demineralized bone matrix is completely

enclosed inside the collagen mesh. In the separately packaged format, an open-ended collagen mesh bag is supplied with separately packaged demineralized bone matrix and is filled and sewn closed with absorbable suture by the clinician. Version 1 of the Porous Biologic Scaffold may be hydrated with blood, saline, or bone marrow aspirate, and are combined with autograft bone prior to implantation.

Version 2 is comprised of a porous resorbable collagen mesh bag either prefilled or separately packaged with activated biphasic ceramic granules. In the prefilled format, the biphasic granules are completely enclosed inside the collagen mesh. In the separately packaged format, an open-ended collagen mesh bag is supplied with separately packaged biphasic granules and is filled and sewn closed with absorbable suture by the clinician. Version 2 of the Porous Biologic Scaffold may be hydrated with blood, saline, or bone marrow aspirate, and are combined with autograft bone prior to implantation.

Both formats of the Porous Biologic Scaffold are supplied terminally sterile and are available in sizes of 18 x 50 mm, 18 x 100 mm, 24 x 50 mm, and 24 x 100 mm.

Summary of Testing

Non-clinical testing was performed in accordance with FDA guidance documents and recognized consensus standards as applicable.

Physical and chemical characterization of the implant materials and finished device was conducted as recommended in the FDA class II bone void filler guidance document. Tests conducted include XRD, FTIR, Trace elements, porosity, surface area, granule size distribution, bulk density, pH, moisture content and handling properties evaluation.

Porous Biologic Scaffold has met all relevant requirements of ISO 10993 biocompatibility testing for permanent bone-contacting implants. Tests for cytotoxicity, genotoxicity, sensitization, irritation/ intracutaneous reactivity, and materials-mediated pyrogenicity were conducted directly on the finished device according to applicable methods within the ISO 10993 panel. Evaluations of sub-acute/sub-chronic toxicity as well as implant reactivity were conducted as part of the rabbit posterolateral spine fusion study. The final device also meets bacterial endotoxin limits of < 20 EU/device according to ANSI/AAMI ST72.

Viral inactivation testing was conducted on the demineralized allograft bone matrix (DBM) component of the Porous Biologic Scaffold, which evaluated a panel of model viruses representing various virus types, sizes, shapes and genomes. The DBM processing methods were determined to provide significant viral clearance potential for a wide range of potential viruses.

The osteoinductive potential of the DBM fibers contained in the Porous Biologic Scaffold is lot tested and verified in an in vivo athymic rodent model, based on demonstrating an osteoinduction score of ≥ 1. Osteoinduction assay results using the athymic rodent assay, or other specified test that has been validated and correlated with the athymic rodent assay, should not be interpreted to predict clinical performance in human subjects.

Implant performance testing was conducted using a posterolateral spine fusion rabbit model to evaluate the safety and performance of the Porous Biologic Scaffold as directly compared to ICBG and the predicate device. Porous Biologic Scaffold demonstrated substantially equivalent new bone formation and spine fusion rates as compared to ICBG and the predicate device via radiographic, biomechanical and histological evaluations across multiple time points.

Substantial Equivalence

Porous Biologic Scaffold has the same intended use, and the same or similar technological characteristics, principles of operation and indications as the predicate devices. Any technological differences presented by the Porous Biologic Scaffold do not raise new questions of safety or effectiveness, as demonstrated by the comparative evaluation in the animal study.