September 2, 2022

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

Re: K221644
Trade/Device Name: Synthetic Bone Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 3, 2022
Received: June 6, 2022

Dear Dr. 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 (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,

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221644

Device Name
Synthetic Bone Putty

Indications for Use *(Describe)*
Synthetic Bone Putty 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. Synthetic Bone Putty is indicated to be packed gently into bony voids or gaps of the pelvis and posterolateral spine and may be used either standalone or in combination 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.

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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
Date Prepared:	June 3, 2022

Device Information:

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

Predicate Device(s):

K140375: Mastergraft Putty (Medtronic Sofamor Danek USA, Inc.)
K132071: Bioactive Bone Graft Putty (BioStructures, LLC)

Indications For Use:

Synthetic Bone Putty 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. Synthetic Bone Putty is indicated to be packed gently into bony voids or gaps of the pelvis and posterolateral spine and may be used either standalone or in combination with autograft as a bone graft extender. The device is resorbed and replaced with host bone during the healing process.

Device Description:

Synthetic Bone Putty is a resorbable bone void filler comprised of biphasic ceramic granules suspended in an alkylene oxide polymer carrier. The device can be used either standalone or in combination with autograft bone as a bone graft extender. Synthetic Bone Putty is supplied terminally sterile in an open-barrel syringe applicator that is packaged in a sterile barrier blister pack. The device is offered in sizes of Small, Medium, and Large.

Summary of Testing:

Non-clinical testing was performed in accordance with FDA guidance documents and recognized consensus standards as applicable. Characterization of the implant materials and was conducted as recommended in the FDA class II bone void filler guidance document and the device meets relevant requirements of ASTM F1185-

03 and F1088-04a. The device has met all ISO 10993 biocompatibility requirements relevant to bone void filler devices. Sterilization, packaging and shelf-life stability evaluations have been performed with passing results.

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

The Bacterial Endotoxins Test (BET) was conducted on the finished device to detect and quantify the presence of bacterial endotoxins. The device met pyrogenicity limit specifications according to FDA-recognized standards ANSI/AAMI ST72:2019, USP <161>, and USP <85>.

Substantial Equivalence:

Synthetic Bone Putty 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 Synthetic Bone Putty do not raise new questions of safety or effectiveness, as demonstrated by the comparative evaluation in the animal studies.

Conclusion:

Performance testing and technological comparisons presented in this 510(k) indicate that the Synthetic Bone Putty is substantially equivalent to the identified predicate devices.