January 18, 2023

Zavation Medical Products, LLC
℅ Robert A. Poggie, Ph.D.
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7W3J6
Canada

Re: K221726
Trade/Device Name: Uni-FuZe-C Bone Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 10, 2022
Received: June 14, 2022

Dear Dr. Poggie:

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,

Sara S. Thompson -S

For

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)*
K221726

Device Name
Uni-FuZe-C Bone Strip

Indications for Use *(Describe)*

Uni-FuZe-C Bone Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Uni-FuZe-C Bone Strip resorbs and is replaced with 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.

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510(k) SUMMARY for Zavation Uni-FuZe-C Bone Strip – K221726

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of Zavation Uni-FuZe-C Bone Strip.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-de-L'Ile-Perrot Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	January 5, 2023

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Zavation Medical Products, LLC
Manufacturer Address:	3670 Flowood Drive, Flowood, MS 39232 USA
Registration Number:	3008583793
Contact Name:	Elke Carter
Title:	Regulatory Manager
Device Trade Name:	Uni-FuZe-C Bone Strip
Device Common Name:	Bone Void Filler
Classification Name:	Filler, bone void, calcium compound
Classification Code:	MQV
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3045

C1. PRIMARY PREDICATE DEVICE

K051386	Medtronic Sofamor Danek USA, MasterGraft Putty

C2. PREDICATE DEVICES

K082166	Medtronic Sofamor Danek USA, MasterGraft Strip
K201781	Zavation Medical Products Uni-FuZe-P Bone Putty

D. DEVICE DESCRIPTION

Zavation Medical's Uni-FuZe-C Bone Strip is a bioactive osteoconductive, resorbable, biocompatible bone graft substitute in strip form. The product is composed of a matrix of purified bovine collagen per ASTM F2212, beta tricalcium phosphate (Beta-TCP per ASTM F1088), and Bioglass 45S5 per ASTM F1538.

E. INDICATIONS FOR USE

Uni-FuZe-C Bone Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Uni-FuZe-C Bone Strip resorbs and is replaced with bone during the healing process.

F. TECHNOLOGICAL CHARACTERISTICS

Zavation Medical's Uni-FuZe-C Bone Strip is a bioactive, osteoconductive, resorbable, biocompatible bone graft substitute in strip form. The product is composed of a matrix of purified bovine collagen per ASTM F2212, beta tricalcium phosphate (Beta-TCP per ASTM F1088), and Bioglass 45S5 per ASTM F1538. The Uni-FuZe-C Bone Strip can be applied directly to the defect site with whole blood hydration. The table below compares characteristics of the subject and predicate devices.

	Subject Device Zavation Uni-FuZe-C Bone Strip	Primary Predicate K051386, Medtronic MasterGraft Putty	Predicate Device K082166, Medtronic MasterGraft Strip	Predicate Device K201781, Zavation Uni-FuZe-P Bone Putty
Regulatory Class, Code	888.3045, MQV	888.3045, MQV	888.3045, MQV	888.3045, MQV
Materials	Beta-TCP, ASTM F1088 Type I bovine collagen, ASTM F2212 Bioglass 45S5, ASTM F1538	Biphasic ceramic that is15% HA & 85% beta TCP Type I bovine collagen	Biphasic ceramic of 15% HA & 85% beta TCP Type I bovine collagen	Beta-TCP, ASTM F1088 Type I bovine collagen, ASTM F2212 Bioglass 45S5, ASTM F1538 Polyethylene glycol (PEG)
Physical form	Strip	Putty	Strip	Putty
Dosage	3, 5, 6, 10, 13, 20 cc	NA	5, 10, 20 cc	2.5, 5.0, 10.0 cc
Resorbable	Yes	Yes	Yes	Yes
Porosity	Highly porous	Highly porous	Highly porous	Highly porous
Sterile, single use	Yes	Yes	Yes	Yes

The subject Uni-FuZe-C Bone Strip and predicate devices are comprised of similar materials (collagen, HA/TCP, bioglass), resorb quickly, similar in size, and can be gently manipulated into bone-voids. Mastergraft putty, the primary predicate device, was used as the control product in the functional animal model for the subject device; the study results support substantial equivalence. The Uni-FuZe-C Bone Strip has similar clinical indications for use as the primary predicate MasterGraft Putty and the same indications as the predicate Uni-FuZe-P Bone Putty.

G. PERFORMANCE DATA

Assessment of biocompatibility of the Uni-FuZe-C Bone Strip was performed according to ISO 10993-1:2018 and biological effects were considered per 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.” Material-Mediated Pyrogenicity, Cytotoxicity, Irritation, Sensitization, Systemic reaction, and Implantation tests demonstrated acceptable biological safety profiles.

Assessment of biocompatibility through implantation was performed per ISO 10993-6 at time points of 4 and 13 weeks. Bone healing and biological response were evaluated using an established rabbit functional femoral critical cancellous bone defect model at time points of 1 day and 6 and 12 weeks following implantation for the subject device Uni-FuZe-C Bone Strip and the primary predicate device MasterGraft Putty. Biological performance was measured using radiographic images, micro-CT, and histological analyses. The macro observations of the implant sites demonstrated healthy tissue absent of adverse inflammatory reactions for Uni-FuZe-C Bone Strip. Radiographic and microCT analyses indicated no adverse reactions and a normal progression in healing over time. Histopathology assessment showed normal osteoconductive healing response. The study confirmed the biocompatibility and normal osteoconductive healing response associated with the Uni-FuZe-C and demonstrated substantially equivalent *in vivo* performance to the primary predicate device across all endpoints.

The 45S5 bioglass, collagen, and β-TCP constituents of the subject device were tested and / or certified as meeting the requirements of ASTM F2212 for Type I bovine collagen, ASTM F1538 for Bioglass 45S5, and ASTM F1088 for the β-TCP.

The subject device was determined to be bioactive per the requirements of ISO 23317. The bioactive glass granules in the Uni-FuZe-C strip precipitated apatite during the in-vitro assessment, while immersed in simulated body fluid per the definition in ISO 23317.

Packaging seal strength and integrity was validated via peel strength (per ASTM F88/F88M) and bubble emission (per ASTM F2096); acceptance criteria were met. Shipping and handling validations was performed per ASTM D7386; acceptance criteria were met. Shelf life was validated for one-year.

Sterilization was validated to SAL of 10^{-6} using method VDmax per ANSI/AAMI/ISO 11137-2: 2013/(R)2019 (VDmax25) with 25 kGy minimum dose. Limulus Amebocyte Lysate (LAL) testing demonstrated the maximum dose for one surgery has less than 20 endotoxin units (< 20 EU).

H. CONCLUSIONS

Uni-FuZe-C Bone Strip has similar indications for use, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between Uni-FuZe-C Bone Strip and the predicate devices do not raise new issues of safety or effectiveness. The performance data demonstrate that Uni-FuZe-C Bone Strip is substantially equivalent to the predicate devices.