



December 28, 2020

Zavation Medical Products, LLC
% Robert Poggie, Ph.D.
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-del-L'Ile-Perrot, QC J7V 7P2
Canada

Re: K201781

Trade/Device Name: Uni-FuZe-P 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: December 2, 2020
Received: December 4, 2020

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,

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

Indications for Use

510(k) Number (if known)

K201781

Device Name

Uni-FuZe-P Bone Putty

Indications for Use (Describe)

Uni-FuZe-P Bone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Uni-FuZe-P Bone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that 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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K201781 SUMMARY for Zavation Uni-FuZe-P Bone Putty

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-P Bone Putty.

A. SUBMITTERS INFORMATION

Submitter Name: BioVera, Inc.
Submitter Address: 65 Promenade Saint-Louis, NDIP, Québec, J7V 7P2,
CANADA
Contact Person: Robert A. Poggie, PhD
Phone and Fax Numbers: 514-901-0796
Date of Submission: June 29, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name: Zavation Medical Products, LLC
Manufacturer Address: 220 Lakeland Parkway
Flowood, MS 39232 USA
Registration Number: 3008583793
Contact Name: Jeffrey Johnson
Title: CEO
Device Trade Name: Uni-FuZe-P Bone Putty
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. REFERENCE DEVICE

K173933 Xenco Medical, LLC, Sorrento Bioglass Bone Graft Substitute

D. DEVICE DESCRIPTION

Uni-FuZe-P Bone Putty is a resorbable bone void filler made from a matrix of bovine collagen (ASTM F2212), beta tricalcium phosphate (Beta-TCP per ASTM F1088), Bioglass 45S5 (ASTM F1538), and polyethylene glycol (PEG, 1450/600 blend). The implant is provided as sterile and is for single use.

E. INDICATIONS FOR USE

Uni-FuZe-P Bone Putty is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Uni-FuZe-P Bone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Uni-FuZe-P Bone Putty is a bioactive osteoconductive, resorbable, biocompatible bone graft substitute in putty form. The product is composed of matrix of bovine collagen per ASTM F2212, beta tricalcium phosphate (Beta-TCP per ASTM F1088), Bioglass 45S5 per ASTM F1538, and polyethylene glycol (PEG, 1450/600 blend). Uni-FuZe-P Bone Putty can be applied directly to the defect site or used as a moldable, and malleable material to be placed at the defect site.

Uni-FuZe-P Bone Putty is similar in composition to the reference device, Xenco Medical's Sorrento Bioglass Bone Graft Substitute, and has similar clinical indications for use as the predicate MasterGraft Putty device and reference Sorrento Bioglass Bone Graft Substitute. The subject, predicate, and reference devices are comprised of similar base materials (collagen, HA / TCP, bioglass), resorbable in relatively short period of time, available in similar volumes, and can be manipulated to fit the bone void. The table below summarizes the technological characteristics of the subject, predicate, and reference devices and supports equivalency of the products.

	Subject Device Zavation Uni-FuZe-P Bone Putty	Predicate Device, K051386, Medtronic MasterGraft Putty	Reference Device, K173933, Sorrento Bioglass Bone Graft
Regulatory Classifications	MQV	MQV	MQV
Materials	Beta-TCP ASTM F1088 Type I bovine collagen per ASTM F2212 Bioglass 45S5 per ASTM F1538 Polyethylene glycol	Beta-TCP and HA Type I bovine collagen	Beta-TCP ASTM F1088 Type I bovine collagen per ASTM F2212 Bioglass 45S5 per ASTM F1538
Physical form	Putty	Putty	Strip
Dosage	2.5, 5, 10 cc		2, 5, 10, 12, 20, 24 cc
Resorbable	Yes	Yes	Yes
Porosity	Granular, high surface area	Granular, high surface area	Granular, high surface area
Sterile and single use?	Yes	Yes	Yes

G. PERFORMANCE DATA

Assessment of biocompatibility of Uni-FuZe-P Bone Putty was performed by Nelson Labs according to ISO 10993-1:2018, and for biological effects according to 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, and Implantation tests demonstrated acceptable biological safety profiles.

Biocompatibility per ISO 10993-6 was confirmed through short- and long-term implantation at time points of 4 and 13 weeks. Bone healing and biological response testing were evaluated using an established rabbit functional femoral critical defect model at time points of 1 day and 6- and 12-weeks following implantation for the subject device Uni-FuZe-P Bone Putty and the predicate device MasterGraft Putty. Biological performance was measured and documented with 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-P Bone Putty. 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-P and demonstrated substantially equivalent *in vivo* performance to the predicate device across all endpoints.

The bioactivity of the bioglass component of the Uni-FuZe-P Bone Putty was confirmed per ISO/FDIS 23317; the presence of HA was verified by SEM and XRD.

The stability of the collagen within the subject device was verified using SDS-Page.

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.

Sterilization was validated to an SAL of 10^{-6} using method VDmax of ANSI/AAMI/ISO 11137-2 with 25 kGy selected as the minimum sterilization 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-P Bone Putty has similar indications for use, technological characteristics, and principles of operation as the predicate and reference devices. The minor technological differences between Uni-FuZe-P Bone Putty and the predicate and reference devices do not raise new issues of safety or effectiveness. The performance data demonstrate that Uni-FuZe-P Bone Putty is substantially equivalent to the predicate device.