Bioventus
% Christine Scifert
Exec VP
MRC-X, LLC
6075 Poplar Ave
Memphis, Tennessee 38119

June 18, 2020

Re: K193513
Trade/Device Name: SIGNAFUSE Bioactive Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 20, 2020
Received: May 22, 2020

Dear Ms. Scifert:

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,

Jesse Muir, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193513

Device Name
SIGNAFUSE Bioactive Bone Graft

Indications for Use *(Describe)*

SIGNAFUSE Bioactive Bone Graft is a bone graft substitute intended for use in bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or result from traumatic injury to the bone. SIGNAFUSE Bioactive Bone Graft is indicated to be combined with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis and posterolateral spine. When used in the posterolateral spine, SIGNAFUSE Bioactive Bone Graft is to be used as an autograft extender. The device resorbs and is replaced by 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.

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510(k) Summary

SIGNAFUSE Bioactive Bone Graft

December 16, 2019

Company:	Bioventus 4721 Emperor Blvd, Suite 100 Durham, NC 27700 USA
Primary Contact:	Christine Scifert, Exec VP of MRC-X, LLC
Company Contact:	Kim Patterson Kelly, Senior Director, Regulatory & Clinical Affairs
Trade Name:	**SIGNAFUSE Bioactive Bone Graft**
Common Name:	Filler, Bone Void, Calcium Compound
Classification:	Class II
Regulation Number:	21 CFR 888.3045 (Resorbable calcium salt bone void filler device)
Panel:	Orthopedic
Product Code:	MQV

Device Description:

SIGNAFUSE Bioactive Bone Graft is a bioactive bone graft substitute comprising biphasic mineral granules and 45S5 bioactive glass suspended in a porous type I collagen matrix. The device is provided sterile and is to be combined with autologous bone marrow aspirate prior to use to facilitate packing into bony defects. The device provides an osteoconductive scaffold that resorbs and guides host bone regeneration during the healing process.

Indications for Use:

SIGNAFUSE Bioactive Bone Graft is a bone graft substitute intended for use in bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or result from traumatic injury to the bone. SIGNAFUSE Bioactive Bone Graft is indicated to be combined with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis and posterolateral spine. When used in the posterolateral spine, SIGNAFUSE Bioactive Bone Graft is to be used as an autograft extender. The device resorbs and is replaced by host bone during the healing process.

Substantial Equivalence:

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate:

- MCP Bone Putty, Bioventus, K160446 (S.E 11/7/2016)

Secondary Predicate:

- Interface Bone Void Filler, Bioventus, K112857 (S.E 12/13/2011)

The subject device is for filling of bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure, like the predicate devices. The subject device is identical in indications and principle of operation to both predicate devices. The subject device contains the same materials used in the predicate devices, but the materials are present in different ratios than in the predicate devices. However, the overall collagen to particulate ratio remains the same between the subject device and the MCP Bone Putty. The geometrical differences between the subject device and the MCP Bone Putty result in more choices of graft volume to allow treatment of different size defects, but do not change the ratio of components within the device.

Performance Testing:

SIGNAFUSE Bioactive Bone Graft is a change to the manufacturer's (Bioventus) own predicate device, MCP Bone Putty (K160446, S.E 11/7/2016) to add bioactive glass (Interface Bone Void Filler, K112857, S.E. 12/13/2011) to the formulation. The SIGNAFUSE Bioactive Bone Graft formulation has been fully characterized to meet the current MCP Bone Putty specifications other than strip dimensions and HA/β-TCP content.

SIGNAFUSE Bioactive Bone Graft has met the ISO 10993 biocompatibility requirements and ANSI/AAMI ST72 bacterial endotoxin requirements relevant to bone void filler devices. The controls on sourcing, collection, and handling of the bovine collagen raw materials used in the manufacture of the SIGNAFUSE are identical to MCP Bone Putty and meet requirements of ISO 22442-2 and ISO 22442-3.

SIGNAFUSE Bioactive Bone Graft is terminally sterilized via gamma irradiation and validated to a sterility-assurance level (SAL) of 10^{-6} according to ANSI/AMMI/ISO 11137-2 (Method VD_{MAX}) with a shelf-life of 3 years.

To ensure that the device still functions as intended, SIGNAFUSE Bioactive Bone Graft was evaluated in a posterolateral spine fusion rabbit model in comparison to the MCP Bone Putty predicate device, as well as a control group. The model and method used was identical to the testing performed in K160446 to gain clearance for MCP Bone Putty. Results confirm the biological safety and normal osteoconductive healing characteristics associated with the SIGNAFUSE Bioactive Bone Graft and demonstrate substantially equivalent in vivo performance to the primary predicate MCP Bone Putty (K160446, 11/7/2016) in an established posterolateral spine fusion rabbit defect model (Boden, ASTM F2307-17).

Conclusion:

Performance testing and technological comparisons presented in this 510(k) indicate SIGNAFUSE Bioactive Bone Graft is substantially equivalent to the predicate devices.