December 5, 2023

Bioventus LLC
% Scott Bruder
Founder & CEO
Bruder Consulting & Venture Group
268 Glen Place
Franklin Lakes, New Jersey 07417

Re: K233490
Trade/Device Name: SIGNAFUSE Bioactive Strip (SBS); SIGNAFUSE Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: October 26, 2023
Received: October 27, 2023

Dear Scott Bruder:

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.

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: 2023.12.05 12:56:54 -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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

SIGNAFUSE Bioactive Strip (SBS);
SIGNAFUSE Putty

Indications for Use *(Describe)*

SIGNAFUSE Bioactive Strip (SBS)
SIGNAFUSE Bioactive Strip (SBS) 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 Strip (SBS) is indicated to be combined with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis, posterolateral spine, and intervertebral disc space. When used in the posterolateral spine, SIGNAFUSE Bioactive Strip (SBS) is to be used as an autograft extender. When used in intervertebral disc space, SIGNAFUSE Bioactive Strip (SBS) is to be used as an autograft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device resorbs and is replaced by host bone during the healing process.

SIGNAFUSE Putty
SIGNAFUSE Putty is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SIGNAFUSE Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, posterolateral spine, and intervertebral disc space fusion procedures). SIGNAFUSE Putty can also be used with autograft as a bone graft extender in the posterolateral spine. When used in intervertebral body fusion procedures, SIGNAFUSE Putty can used on its own or as a bone graft extender, and with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device provides a bone void filler that 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
Kellie Stefaniak
Vice President, Global Regulatory & Quality
Bioventus LLC
4721 Emperor Blvd, Suite 100
Durham, NC 27703

Correspondent
Scott Bruder, MD, PhD
Founder and CEO
Bruder Consulting & Venture Group
Scott@BruderConsulting.com
201.874.9701

Date Prepared December 1, 2023

Device

Trade Name	SIGNAFUSE Bioactive Strip (SBS) SIGNAFUSE Putty
Common Name	Bone void filler
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV
Panel	Orthopedic

Predicates

Primary Predicate	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Devices	Bioventus – SIGNAFUSE Bioactive Bone Graft (K193513) Bioventus –Bioactive Bone Graft Putty (K132071)

Device Description
SIGNAFUSE Bioactive Strip (SBS) is a bioactive bone graft substitute comprising biphasic mineral granules and 45S5 bioactive glass suspended in a porous type I collagen matrix, and it identical to the device cleared in K193513. SIGNAFUSE Putty is a bioactive bone graft substitute comprising biphasic mineral granules and 45S5 bioactive glass suspended in an alkylene oxide polymer (AOP) resorbable carrier and is identical to the device cleared in K132071. The SIGNAFUSE Family of devices are single use implants in contact with bone that are sterilized by irradiation with a sterility assurance level (SAL) of 10^{-6}. This submission expands the SIGNAFUSE Family indication to include use in the intervertebral space.

Indications for Use Statement

SIGNAFUSE Bioactive Strip (SBS)

SIGNAFUSE Bioactive Strip (SBS) 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 Strip (SBS) is indicated to be combined with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis, posterolateral spine, and intervertebral disc space. When used in the posterolateral spine, SIGNAFUSE Bioactive Strip (SBS) is to be used as an autograft extender. When used in intervertebral disc space, SIGNAFUSE Bioactive Strip (SBS) is to be used as an autograft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device resorbs and is replaced by host bone during the healing process.

SIGNAFUSE Putty

SIGNAFUSE Putty is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SIGNAFUSE Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, posterolateral spine, and intervertebral disc space fusion procedures). SIGNAFUSE Putty can also be used with autograft as a bone graft extender in the posterolateral spine. When used in intervertebral body fusion procedures, SIGNAFUSE Putty can used on its own or as a bone graft extender, and with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

Substantial Equivalence

The intended use is the same for subject and predicate devices. The subject device and predicates are all indicated for use as bone void fillers in the intervertebral body space.

There are differences in the device's material composition, but these do not raise different questions of safety and effectiveness. The effect of differences in material composition is addressed in clinical rationale.

Performance

The subject devices have been previously cleared under K193513 (SIGNAFUSE Bioactive Strip (SBS)) and K132071 (SIGNAFUSE Putty), which serve as Reference Devices. These submissions are leveraged to support the device's sterility, shelf-life, endotoxin, biocompatibility, and characterizations/bench performance as recommended in FDA's *Class II Special Controls Guidance Document for Resorbable Calcium Salt Bone Void Filler Devices*. The devices' performance in the intervertebral body space was supported by a clinical rationale of bone grafting materials in the intervertebral space.

Summary

The subject device and predicates have the same intended use, and the same specific indications for use in the intervertebral body space. Any differences in technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness. Based on the clinical rationale, the device is substantially equivalent to the predicates.