DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 13, 2017

Bioventus, LLC
% Patsy Trisler, J.D., R.A.C.
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K162860
Trade/Device Name: MCS 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: December 28, 2016
Received: December 28, 2016

Dear Ms. Trisler:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162860

Device Name

MCS Bone Graft

Indications for Use *(Describe)*

MCS 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. MCS Bone Graft is indicated to be hydrated with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis and posterolateral spine. When used in the posterolateral spine, MCS Bone Graft is to be used as an autograft extender. Following implantation, the graft 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information:

Name: Bioventus, LLC

Address: 4721 Emperor Boulevard, Suite 100
Durham, NC 27703

Contact Person: John Brunelle, PhD
Chief Technology Officer – Surgical

Telephone: (949) 553-1717

Date Prepared: February 6, 2017

Device Information:

Trade Name: MCS Bone Graft

Common Name: Bone graft substitute

Classification: Class 2

Regulation: 888.3045, Resorbable calcium salt bone void filler device

Product Code: MQV

Predicate Device(s):

K142276: MCS Bone Graft (BioStructures, LLC)
K071813: Mastergraft® Putty (Medtronic Sofamor Danek)

Background:

MSC Bone Graft has been previously cleared as a bone filler device under 510(k) submission K142276 with indications for use in osseous defects of the extremities and pelvis when mixed with bone marrow aspirate. The purpose of the current submission is to obtain clearance for an additional indication for use in the posterolateral spine when mixed with bone marrow aspirate and combined with autologous bone.

Indications for Use:

MCS 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. MCS Bone Graft is indicated to be hydrated with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis and posterolateral spine. When used in the posterolateral spine, MCS Bone Graft is to be used as an autograft extender. Following implantation, the graft resorbs and is replaced by host bone during the healing process.

Device Description:

MCS Bone Graft is a bone graft substitute comprising biphasic mineral granules suspended in a porous, bovine type I collagen matrix. The biphasic granules are 60% hydroxyapatite (HA) and 40% beta tri-calcium phosphate (βTCP). The device is provided in a strip form and is supplied terminally sterile for single patent use. The device is designed to be combined with autologous bone marrow aspirate prior to implantation to facilitate packing into bony defects and is used with autologous bone in the posterolateral spine. The device provides an osteoconductive scaffold that resorbs and guides host bone regeneration during the healing process.

Performance Testing:

Non-Clinical Testing:

Non-clinical testing was performed in accordance with FDA guidance documents and recognized consensus standards as applicable. Physical and chemical characterization of the implant raw materials and finished device was conducted as recommended in the FDA class II bone void filler guidance document and meet relevant requirements of ASTM F1185-03, F1088-04a and F2212-11. The collagen raw materials meet essential safety requirements for medical devices utilizing animal tissues according to ISO 22442. The device has met biocompatibility requirements for permanent tissue/bone implants according to FDA's Guidance for Industry and Food and Drug Administration Staff: *"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*. Viral inactivation, sterilization, packaging and shelf life stability evaluations have been performed with passing results.

In Vivo Performance Testing:

Animal performance testing was conducted to demonstrate the safety and performance of the MCS Bone Graft as directly compared to the predicate devices. In the prior 510(k) submission (K142276), the MCS Bone Graft was evaluated in a critical-size rabbit femoral defect study and deemed substantially equivalent to Vitoss Scaffold Foam. In the current submission, the MCS Bone Graft was evaluated in a rabbit posterolateral spine fusion study, which demonstrates substantially equivalent spine fusion performance compared to the predicate device and control group (iliac crest bone graft). Outcomes were determined using radiographic, microCT, biomechanical and histological endpoints, measured at 4, 8 and 12 weeks after surgery.

Substantial Equivalence:

MCS Bone Graft has the same intended use, and the same or similar technological characteristics, principles of operation and indications as the predicate devices. The material composition of the MCS Bone Graft is identical to the previously cleared MCS Bone Graft and similar to the Mastergraft Putty. All devices comprise biphasic granules (mixture of hydroxyapatite and beta-tricalcium phosphate) and bovine type I collagen. MCS Bone Graft is provided in strip form and has >90% implant porosity, same as the previously cleared MCS Bone Graft. MCS Bone Graft is supplied sterile and is combined with bone marrow aspirate prior to use, same as both predicates. MCS Bone Graft is to be used with autologous bone in the posterolateral spine, same as Mastergraft Putty. Any technological differences presented by the MCS Bone Graft do not raise new issues of safety or effectiveness.

Conclusion:

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