DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 7, 2016

BioStructures, LLC
% Ms. Patsy J. Trisler
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Ave
Chevy Chase, Maryland 20815

Re: K160446
Trade/Device Name: MCP 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: September 23, 2016
Received: September 23, 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 yours,

Vincent J. Devlin -S

for

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)*
K160446

Device Name

MCP Bone Putty

Indications for Use *(Describe)*

MCP Bone Putty 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. MCP Bone Putty 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, MCP Bone Putty 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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Section 5
510(k) Summary

Submitter Information:

Name:	BioStructures, LLC
Address:	1201 Dove Street, Suite 470 Newport Beach, CA 92660
Contact Person:	John Brunelle, PhD Chief Technology Officer
Telephone:	(949) 553-1717
Date Prepared:	February 17, 2016

Device Information:

Trade Name:	MCP Bone Putty
Common Name:	Bone void filler/ Bone graft substitute
Classification:	Class 2
Regulation:	888.3045, Resorbable calcium salt bone void filler device
Product Code:	MQV

Predicate Device(s):

K032288: Vitoss Foam Bone Graft Substitute (Orthovita, Inc.)
K142276: MCS Bone Graft (BioStructures, LLC)
K071813: Mastergraft® Putty (Medtronic Sofamor Danek)

Indications for Use:

MCP Bone Putty 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. MCP Bone Putty 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, MCP Bone Putty is to be used as an autograft extender. The device resorbs and is replaced by host bone during the healing process.

Device Description:

MCP Bone Putty is a bone graft substitute comprising biphasic mineral granules suspended in a porous type I collagen matrix, provided terminally sterile and for single patient use. The device is to be combined with autologous bone marrow aspirate to facilitate packing into bony defects and upon implantation, provides an osteoconductive scaffold that resorbs and guides host bone regeneration during the healing process.

Performance 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 all ISO 10993 biocompatibility requirements relevant to bone void filler devices. Viral inactivation, sterilization, packaging and shelf life stability evaluations have been performed with passing results.

Animal performance testing was conducted using established rabbit defect models to evaluate the safety and performance of the MCP Bone Putty as directly compared to the predicate devices, as described below.

Femoral Defect Animal Study

The device was evaluated in a critical-sized bilateral femoral defect rabbit model in comparison to the Vitoss predicate. The study included 14 defect sites implanted with the MCP Bone Putty and 12 defect sites for the predicate (19 rabbits total), evaluated at time points of 1 day, 6 weeks and 12 weeks after surgery. Both test groups were fully hydrated with autologous bone marrow aspirate prior to implantation. Defects were created in the medial femoral condyles of each rabbit using a surgical drill bit, followed by implantation of the hydrated graft materials. There were no device-related adverse reactions observed regardless of test group or time point. The safety and performance of MCP Bone Putty were evaluated via macroscopic, radiographic, microCT and histological assessments of the implant site. The study demonstrated that the MCP Bone Putty can safely support bone healing in critical-sized femoral defects in equivalence to the Vitoss predicate device.

Posterolateral Spine Fusion Animal Study

The device was evaluated in a posterolateral spine fusion rabbit model in comparison to the Mastergraft Putty predicate device, as well as a control group using autologous iliac crest bone graft. The study included 25 rabbits and per test group, evaluated at 4 weeks (N=5), 8 weeks (N=8) and 12 weeks (N=12) after surgery. Both the MCP Bone Putty and predicate test groups were fully hydrated with autologous bone marrow aspirate and admixed with autograft bone prior to implantation. Graft materials were implanted bilaterally across the L5-L6 transverse processes. There were no device-related adverse reactions observed regardless of test group or time point. The safety and performance of MCP Bone Putty were evaluated via macroscopic, radiographic, microCT, biomechanical and histological assessments of the fusion site. The study demonstrated that the MCP Bone Putty, when used as an autograft extender, can safely support spine fusion healing in equivalence to both the Mastergraft Putty predicate and iliac crest autograft control.

Substantial Equivalence:

MCP Bone Putty has the same intended use, and the same or similar technological characteristics, principles of operation and indications as the predicate devices. MCP Bone Putty, MCS Bone Graft and Mastergraft Putty are all comprised of biphasic mineral granules (mixture of hydroxyapatite and β-tricalcium phosphate) and bovine type I collagen. Similarly, the Vitoss predicate comprises β-tricalcium phosphate granules and bovine type I collagen. MCP Bone Putty is provided in strip form, similar to all predicates, and has >90% implant porosity, same as the MCS Bone Graft and Vitoss predicates. The MCP Bone Putty finished device is supplied sterile and is combined with bone marrow aspirate prior

to use, same as all predicates. MCP Bone Putty is to be used as an autograft extender when used in the posterolateral spine, same as Mastergraft Putty. Any technological differences presented by the MCP Bone Putty do not raise new issues of safety or effectiveness, as demonstrated by the comparative evaluation in the animal studies.

Conclusion:

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