510(k) SUMMARY

Submitter Name:	BioStructures, LLC
Submitter Address:	1201 Dove Street, Suite 470 Newport Beach, CA 92660
Contact Person:	John Brunelle, Ph.D. Director of R&D/ Manufacturing
Phone Number:	949.553.1717
Date Prepared:	July 2, 2013
Device Trade Name:	Bioactive Bone Graft Putty
Device Classification:	Class II
Classification Name:	Filler, Bone Void, Calcium Compound
Classification Number:	21 CFR 888.3045
Product Code:	MQV
Predicate Device(s):	K071206, Actifuse® ABX, ApaTech Limited K043005, MBCP™, Biomatlante K112857, Interface Bone Void Filler, BioStructures, LLC K020078, Exactech Resorbable Bone Paste, Exactech, Inc.
Indications for Use Statement:	Bioactive Bone Graft 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. Bioactive Bone Graft Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine fusion procedures). Bioactive Bone Graft Putty can also be used with autograft as a bone graft extender in the posterolateral spine. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.
Device Description:	Bioactive Bone Graft Putty is a synthetic bone void filler comprised of a mixture of calcium phosphate granules and bioactive glass granules suspended in a resorbable polymer carrier that facilitates handling and delivery of the granule components. The device is supplied as putty, pre-loaded in a syringe applicator and packaged in a sterile barrier foil pouch. The device is provided sterile, for single use, in a variety of sizes.
Summary of Testing:	Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidance documents as applicable. Raw materials characterization testing was performed according to ASTM standards: F1538-03, F1185-03, F1088-04a, F1929/F0926M and USP NF.

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Biocompatibility testing, according to ISO 10993 for a long-term implant product, demonstrated the device is biocompatible and non-toxic.

Packaging, sterilization and shelf life testing according to the following standards were presented in the 510(k):

- Packaging: ISO11607, ASTM F2096-11, F88-09 and F1929-98; and ISO 11137.
- Sterilization and Shelf Life; ISO 11137 and ASTM F1980.

The device is considered bioactive based on in vitro studies that show apatite layer formation on the surface of the implant following immersion in simulated body fluid (SBF). These results have not been correlated to clinical performance.

Animal performance testing was performed in femoral cancellous defect and posterolateral spine fusion (PLF) rabbit models to evaluate the safety and performance of the Bioactive Bone Graft Putty compared to a predicate device. The test results showed equivalent in vivo performance in safety, graft resorption and new bone formation.

Comparison to the Predicate Devices:

Bioactive Bone Graft Putty has the same intended use and the same principles of operation as all the predicates, which serve as osteoconductive matrices for new bone formation.

Bioactive Bone Graft Putty is similar technologically to the four predicates.

The technological differences presented by the composition of materials in Bioactive Bone Graft Putty do not raise new issues of safety or effectiveness, as demonstrated by the side-by-side evaluation in the animal performance studies.

Substantjal Equivalence Conclusion:

The comparisons and study data presented in the 510(k) lead to the conclusion that Bioactive Bone Graft Putty is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2014

BioStructures, LLC
% Patsy J. Trisler, JD, RAC
Trisler Consulting
5600 Wisconsin Avenue #509
Chevy Chase, Maryland 20815

Re: K132071
Trade/Device Name: Bioactive Bone Graft 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, 2013
Received: December 3, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132071

Device Name: Bioactive Bone Graft Putty

Indications for Use:

Bioactive Bone Graft 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. Bioactive Bone Graft Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine fusion procedures). Bioactive Bone Graft Putty can also be used with autograft as a bone graft extender in the posterolateral spine. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132071