510(k) Summary
BioSphere™ Bioactive Bone Graft

APR 1 9 2013

1. **Submitter Information:**

Synergy Biomedical, LLC
400 Franklin Ave
Suite 207
Phoenixville, PA 19460

Date Prepared: September 17th, 2012

2. **Contact Information:**

Jonathan Kahan
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

3. **Device Name and Classification:**

Product Name:	BioSphere Bioactive Bone Graft Putty
Common Name	Bone Void Filler
Classification Name:	Resorbable Calcium Salt Bone Void Filler Device
Proposed Classification:	21 CFR 888.3045
Classification Panel:	Orthopedic
Product Code:	MQV
Device Class:	Class II

4. **Predicate Device(s)**
Novabone Putty – Bioactive Synthetic Graft (K060728)
Intergro DBM (K031399)

5. **Device Description**
BioSphere Putty is an osteoconductive, bioactive bone void filler that, like its predicate device (NovaBone), is composed of 45S5 bioactive glass particles. In BioSphere Putty, the bioactive glass is mixed with an inert, moldable carrier that aids in placement of the product into bony voids. Upon implantation, the carrier is absorbed by the site and the remaining bioactive glass particles provide an osteoconductive surface for bone formation. The bioactive glass particles are provided in a spherical form, and the natural packing of the spheres creates 3-dimensional, interconnected porosity that allows for bone regeneration throughout the defect site.

6. **Intended Use**
BioSphere Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BioSphere Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous

defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

7. **Performance Data**

The primary component of BioSphere Putty is medical grade 45S5 bioactive glass which complies with the requirements of ASTM F-1538. Testing of the device in accordance with ISO 10993 Biological Evaluation of Medical Device demonstrated that the materials are biocompatible. Comparative testing using XRD, XRF, particle size analysis, and ion dissolution showed that the bioactive glass component was identical to the predicate device. In vitro bioactivity testing of the Putty showed that the bioactive glass particles were capable of forming a calcium phosphate layer when incubated in simulated body fluid. Additionally, performance of the device in a clinically relevant animal model showed bone formation similar to the predicate device. These results have not been correlated to clinical performance.

8. **Substantial Equivalence**

BioSphere Putty is as safe and effective as the predicate devices. BioSphere Putty has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological difference between BioSphere Putty and its predicate devices, the use of a spherical particles and the inclusion of an inert, moldable carrier, raises no new issues of safety or effectiveness. Performance data demonstrate that BioSphere Putty is as safe and effective as the predicates. Thus, BioSphere Putty is substantially equivalent.

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

Synergy Biomedical, LLC
% Hogan Lovells US LLP
Mr. Jonathan S. Kahan
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Letter dated: April 19, 2013

Re: K122868
Trade/Device Name: BioSphere Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV
Dated: February 27, 2013
Received: February 27, 2013

Dear Mr. Kahan:

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" (21CFR 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: BioSphere Putty

Indications for Use:

BioSphere Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BioSphere Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (*i.e.*, the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122868

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