JUL 16 2014

510(k) Summary
BioSphere® Putty Bioactive Bone Graft

1. Submitter Information:

Synergy Biomedical, LLC
100 Springhouse Dr
Suite 108
Collegeville, PA 19426

Date Prepared. April 1, 2014

2. Contact Information:

Randy Prebula
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

3. Device Name and Classification:

Product Name.	BioSphere Putty Bioactive Bone Graft
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)

BioSphere Putty (K122868)
Novabone Putty – Bioactive Synthetic Graft (K080009)
InterGro DBM (K082793)

5. Device Description

BioSphere Putty Bioactive Bone Graft (BioSphere Putty) is an osteoconductive, bioactive bone void filler that, like its predicate device, 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. In the posterolateral spine, BioSphere Putty can be combined with autograft as a bone graft extender.

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 as a bone void filler in the extremities and pelvis, and as a bone graft extender in the posterolateral spine 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. The composition and formula used in BioSphere Putty is identical the BioSphere Putty predicate. Expansion of the device indications, to include use as a bone graft extender for posterolateral fusion, is supported by performance testing of the device in a clinically relevant spinal animal model. Using a rabbit posterolateral fusion model, the device (BioSphere Putty + autograft) was compared to autograft in order to demonstrate substantial equivalence to the predicate. In the study, spines were evaluated at 6 and 12 weeks using x-ray, microCT, histology, and histomorphometry. Additionally at 12 weeks, spines were biomechanically tested in range of motion and tensile peak load. The radiographic fusion rate for each group was determined from the 12 week x-rays and microCT images by conducting a blinded, bilateral radiographic fusion assessment. Five (5) animals were evaluated at each time point for each group. The results showed that the device was similar to autograft at both time points.

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 devices. In vivo performance data demonstrated that BioSphere Putty is as safe and effective as autograft. Thus, BioSphere Putty is substantially equivalent to the predicates.

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

July 16, 2014

Synergy Biomedical, LLC
% Mr. Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K140844
Trade/Device Name: BioSphere Putty Bioactive Bone Graft (BioSphere Putty)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: April 17, 2014
Received: April 17, 2014

Dear Mr. Prebula:

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" (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 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,

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)*
K140844

Device Name
BioSphere Putty Bioactive Bone Graft (BioSphere Putty)

Indications for Use *(Describe)*
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 as a bone void filler in the extremities and pelvis, and as a bone graft extender in the posterolateral spine. 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140844

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