January 19, 2018

Synergy Biomedical, LLC
% Randy Prebula
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street, N.W.
Washington, District of Columbia 20004

Re: K173301
Trade/Device Name: BioSphere MIS Putty (BioSphere MIS)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 22, 2017
Received: December 22, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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 on last page

510(k) Number *(if known)*

K173301

Device Name:

BioSphere MIS Putty (BioSphere MIS)

Indications for Use *(Describe)*

BioSphere MIS Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BioSphere MIS 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)

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

BioSphere® MIS Putty

1. Submitter Information:

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

Date Prepared: December 22, 2017

2. Contact Information:

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

3. Device Name and Classification:

Product Name:	BioSphere MIS Putty
Common Name:	Bone Void Filler
Classification Regulation:	21 CFR § 888.3045
Classification Name:	Resorbable Calcium Salt Bone Void Filler Device
Classification Panel:	Orthopedic
Product Code:	MQV
Device Class:	Class II

4. Predicate Device:

BioSphere Putty (K140844, K122868)

5. Device Description and Summary of Technological Characteristics:

BioSphere MIS Putty ("BioSphere MIS") is an osteoconductive, bioactive bone void filler that, like its predicate device, is composed primarily of medical-grade 45S5 bioactive glass particles. The composition and formula of this material is unchanged and is identical to that used in the BioSphere Putty predicate. The bioactive glass is mixed with an inert, moldable carrier using the exact same composition and formula as used in the predicate device.

The only difference between the two devices is that BioSphere MIS Putty is supplied in a prefilled cannula with a delivery gun to aid with placement into certain types of bony voids that are otherwise difficult to reach. The manner in which the device is delivered to the target site does not play any role in the putty achieving its intended clinical purpose (i.e., supporting bone regeneration).

Upon implantation of BioSphere MIS Putty into the target site, 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 supplied 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. This is the same mechanism of action as with the predicate. In the posterolateral spine, BioSphere MIS Putty can be combined with autograft as a bone graft extender in the same manner as the predicate BioSphere Putty.

6. Intended Use / Indications for Use:

BioSphere MIS Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BioSphere MIS 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. Purpose of 510(k):

The purpose of this 510(k) is to modify the BioSphere Putty (K140844) by supplying the final putty formulation pre-filled in a cannula, with a delivery gun, instead of in an open bore syringe. This modification is being made to enhance access of the device to bony voids or gaps that are within the cleared predicate's indications for use, but were previously difficult to reach – namely, deep graft sites and graft sites resulting from minimally invasive surgery.

8. Performance Data:

BioSphere MIS Putty was characterized by a variety of quantitative tests and qualitative assessments.

- Putty extrusion was evaluated by measuring the dispensed putty amount following each pull of the delivery gun trigger. The results showed that the delivery gun was able to extrude a reproducible amount of putty for each trigger pull.
    - Assessments of putty extrusion were also conducted using room temperature and refrigerated samples to mimic colder operating room temperatures. Additionally, extrusion was evaluated with an open and partially blocked cannula end. The delivery gun was effective in extruding putty from the cannula regardless of putty temperature, and was able to extrude the putty through a partially blocked end.
- A 3-point bending test was used to demonstrate that the cannulas did not critically fail resulting in fracture pieces or broken edges. All cannulas preferentially failed through plastic deformation, as seen by buckling and bending of the cannula.
- A qualitative assessment of the delivery gun assembly showed that the cannula was easily attached and a stable attachment was maintained during putty extrusion.
- Confirmatory testing of the BioSphere MIS Putty components showed the product was non-cytotoxic and had acceptable endotoxin levels.

9. Conclusion:

BioSphere MIS Putty is as safe and effective as the predicate device. BioSphere MIS Putty has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The only difference between the modified device and the cleared predicate (change in delivery mechanism from an open bore syringe to a cannula with delivery gun) does not impact its function as a bone void filler and raise no new issues of safety or effectiveness. Thus, BioSphere MIS Putty is substantially equivalent to the predicate.