December 20, 2024

Synergy Biomedical
℅ Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
268 Glen Pl
Franklin Lakes, New Jersey 07417

Re: K241167
Trade/Device Name: BioSphere MIS 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 25, 2024
Received: April 26, 2024

Dear Scott Bruder:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.12.20 11:54:16 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K241167

Device Name

BioSphere MIS Putty

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 and intervertebral disc space. When used in intervertebral disc space, BioSphere MIS Putty is to be used as an autograft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler. 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.

K241167

510(k) Summary

Submitter
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Chief Executive Officer (CEO)
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Date Prepared
December 18, 2024

Device

Trade Name	BioSphere MIS Putty
Common Name	Bone void filler
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV
Panel	Orthopedic

Predicates

Primary Predicate	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Device	Synergy Biomedical – BioSphere MIS Putty (K173301)

Device Description
BioSphere MIS Putty device is composed primarily of medical-grade 45S5 bioactive glass particles. The composition and formula of this material are unchanged and identical to that used in the BioSphere Reference Device (K173301). This submission expands the device's indication to include use in the intervertebral spine and incorporates minor changes to the applicator, delivery gun, and packaging.

Indications for Use Statement
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 and intervertebral disc space. When used in intervertebral

disc space, BioSphere MIS Putty is to be used as an autograft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler. 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.

Substantial Equivalence

The intended use is the same for subject and predicate devices. There are differences in the device's material composition and delivery system, but this does not raise different questions of safety and effectiveness. Specifically, the K203714 predicate consists of ceramic granules premixed with a polymeric binder while the K222276 predicate is made from 45S5 bioactive glass in a polymeric carrier in an open-bore syringe. From its technological characteristics, BioSphere MIS is most similar to the K222276 predicate, as both are putties primarily of bioactive glass, but differing in applicator (MIS versus open-bore syringe). The effect of differences in material composition and applicator is addressed in the prior functional animal model performance.

Performance

The subject device has been previously cleared under K173301, which serves as a Reference Device. This submission is leveraged to support the device's sterility, shelf-life, endotoxin, pyrogenicity, biocompatibility, and characterizations/bench performance as recommended in FDA's *Class II Special Controls Guidance Document for Resorbable Calcium Salt Bone Void Filler Devices*. The device's performance in the intervertebral body space was supported by a robust analysis of bone grafting materials in the prior posterolateral spine fusion studies.

Summary

The subject device and predicates have the same intended use, and the same specific indications for use in the intervertebral body spine. Any differences in technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness. Based on the clinical analysis, the device is substantially equivalent to the predicates.