October 2, 2023

SurGenTec, LLC
Travis Greenhalgh
CEO
911 Clint Moore Rd
Boca Raton, Florida 33487

Re: K231716
Trade/Device Name: OsteoFlo® HydroPutty™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: August 31, 2023
Received: August 31, 2023

Dear Travis Greenhalgh:

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.

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: 2023.10.02 13:40:35 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231716

Device Name

OsteoFlo® HydroPutty™

Indications for Use *(Describe)*

OsteoFlo® HydroPutty™ is indicated for bony voids or gaps of the skeletal system (i.e., the extremities and pelvis) 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. The device provides a bone void filler that is resorbed and replaced with host 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

Device Trade Name: OsteoFlo® HydroPutty™

Manufacturer: SurGenTec, LLC
911 Clint Moore Rd,
Boca Raton, FL 33487

Contact: Travis Greenhalgh
CEO
561.990.7882

Date Prepared: September 28, 2023

Classification: Class II per 21 CFR 888.3045: Resorbable calcium salt bone void filler device

Product Codes: MQV

Primary Predicate: NovaBone Putty (K110368)

Additional Predicate: OsteoFlo NanoPutty (K200064)

Indications For Use:
OsteoFlo® HydroPutty™ is indicated to fill bony voids or gaps of the skeletal system (i.e. the extremities and pelvis) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or the result of traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

Device Description:
The OsteoFlo® HydroPutty™ is a resorbable bone void filler comprised of porous carbonated apatite granules and bioglass, in a synthetic polymer binder. The OsteoFlo® HydroPutty™ is intended to be easily packed into osseous defects. The single-use device is supplied sterile via gamma radiation and dry. The device requires mixing with aqueous sterile saline solution in a 1:1 ratio prior to use. The OsteoFlo® HydroPutty™ is supplied as either a pre-filled syringe or vial, in 1, 2.5, 5 and 10mL configurations.

Predicate Device:
The OsteoFlo® HydroPutty™ is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: NovaBone Putty (K110368)
Additional Predicate: OsteoFlo NanoPutty (K200064)

The subject and predicate devices have the same device characteristics (sterile, single-use, synthetic bone void filler which are applied as a malleable putty). These devices serve as absorbable scaffolds for new bone formation to repair orthopedic osseous defects in the skeletal system that are not intrinsic to the stability of the bony structure, and which are surgically created or the results of traumatic injury. The differences in physical component chemistry, particle format, or form do not impact device function. With no differences in biocompatibility, general intended use, or method of operation, the OsteoFlo® HydroPutty™ is determined to be substantially equivalent to the cited predicate devices.

Performance Testing Summary:
The following non-clinical performance data were provided to demonstrate substantial equivalence of the subject device to the predicate.

- Biocompatibility evaluation per ISO 10993-1:2018
- Sterilization validation per ISO 11137-1:2006 and ISO 11137-2:2013
- Packaging validation per ISO 11607-1:2009 and ISO 11607-2:2006
- Shelf-life testing per ASTM 1980-16
- Bacterial endotoxin testing per ANSI/AAMI ST72:2019
- Material characterization, including x-ray diffraction, particle size, and particle porosity and surface area
- *In vivo* evaluation in a critical-size rabbit femoral defect model Routine monitoring for bacterial endotoxins will be conducted per AAMI ST72:2019

Substantial Equivalence:
In summary, non-clinical testing conducted on the OsteoFlo® HydroPutty™ demonstrates that the device is substantially equivalent to the predicate devices. Effectiveness, in terms of device absorption and bone formation, has been shown in the animal study, with no new risks to biological safety, device sterility, or packaging raised by other validation testing.

Clinical Data:
No clinical tests were submitted or relied upon in this premarket notification submission to support a decision of substantial equivalence.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. OsteoFlo® HydroPutty™ is as safe, as effective, and performs as well as, or better, than the predicate devices.