



December 23, 2024

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

Re: K242797

Trade/Device Name: OsteoFlo HydroFiber
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: November 27, 2024
Received: November 27, 2024

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.

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 - Digitally signed by JESSE
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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

Indications for Use

510(k) Number (if known)

K242797

Device Name

OsteoFlo® HydroFiberTM

Indications for Use (Describe)

OsteoFlo HydroFiber is a bone void filler intended for use in osseous defects of the skeletal system that are not intrinsic to the stability of the bony structure i.e., the pelvis, intervertebral disc space, and posterolateral spine. These defects may be surgically created or the result of traumatic injury to the bone. OsteoFlo HydroFiber is indicated to be packed gently into bony voids or gaps of the pelvis, posterolateral spine, or intervertebral disc space, and may be used either standalone or in combination with autograft as a bone graft extender. The device is resorbed and replaced with host bone during the healing process. When used in intervertebral body fusion procedures, OsteoFlo HydroFiber must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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® HydroFiber™

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

Contact: Travis Greenhalgh
CEO
SurGenTec, LLC
travis@surgentec.com

Date Prepared: December 23, 2024

Classifications: 21 CFR 888.3045: Resorbable Calcium Salt Bone Void Filler

Class: II

Product Codes: MQV

Primary Predicate: MASTERGRAFT Putty (K140375)

Additional Predicate: Vitoss (K163621)

Additional Predicate: Synthetic Bone Putty (K240458)

Indications For Use:

OsteoFlo HydroFiber is a bone void filler intended for use in osseous defects of the skeletal system that are not intrinsic to the stability of the bony structure i.e., the pelvis, intervertebral disc space, and posterolateral spine. These defects may be surgically created or the result of traumatic injury to the bone. OsteoFlo HydroFiber is indicated to be packed gently into bony voids or gaps of the pelvis, posterolateral spine, or intervertebral disc space, and may be used either standalone or in combination with autograft as a bone graft extender. The device is resorbed and replaced with host bone during the healing process. When used in intervertebral body fusion procedures, OsteoFlo HydroFiber must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Device Description:

OsteoFlo HydroFiber is a resorbable bone void filler comprised of calcium phosphate, bioglass, in a synthetic polymer binder. The OsteoFlo HydroFiber is intended to be easily packed into osseous defects. The single-use device is supplied sterile and dry. The device requires mixing with aqueous solution (autograft, saline, or bone marrow aspirate) prior to

use. OsteoFlo HydroFiber may be used as standalone, equivalent to autograft, or in conjunction with autograft.

Predicate Device:

The OsteoFlo HydroFiber 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: MASTERGRAFT Putty, Medtronic (K140375)

Predicate Device: Vitoss, Stryker (K163621)

Performance Testing Summary:

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

- Biocompatibility 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
- Material characterization, including x-ray diffraction, particle size, and particle porosity and surface area
- *In vivo* evaluation in a Lapine Posterolateral Fusion Model

Technological Similarities / Differences:

The subject and predicate devices are all resorbable calcium salt bone void fillers intended to fill osseous defects of the skeletal system. The subject device and predicate devices include a binder that is resorbed to expose calcium phosphate-based particles. The particles act as an osteoconductive scaffold for new bone formation as they are slowly resorbed. The material composition of the subject device varies from the predicate devices, however, biocompatibility evaluations, material characterizations and an *in vivo* evaluation of the subject device demonstrate that the difference in material composition does not raise different questions of safety and effectiveness, and the subject device is substantially equivalent to the cited predicates.

Substantial Equivalence:

In summary, testing conducted on the OsteoFlo HydroFiber demonstrates that the device is substantially equivalent to the predicate devices.

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 HydroFiber is as safe, as effective, and performs as well as, or better, than the predicate devices.