May 28, 2025

SurGenTec, LLC
Guilherme Pires
Vice President of Operations
911 Clint Moore Rd
Boca Raton, Florida 33487

Re: K243949
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: April 18, 2025
Received: April 21, 2025

Dear Mr. Pires:

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: 2025.05.28 16:14:07 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K243949

Device Name

OsteoFlo HydroFiber

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 extremities, 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 extremities, 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.**

*510(k) Summary* *K243949*

**Device Trade Name:** OsteoFlo HydroFiber

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

**Contact:** Guilherme Pires
VP of Operations
SurGenTec, LLC
gui@surgentec.com

**Date Prepared:** May 5, 2025

**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), OsteoFlo HydroFiber (K242797)

**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 extremities, 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 extremities, 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:**
The OsteoFlo® HydroFiber™ is a resorbable bone void filler designed to be placed in bony defects, either surgically created (i.e., tumor removal), or the result of traumatic injury. The single-use device is supplied sterile and dry. The device requires mixing with aqueous solution (autograft, saline, blood, or bone marrow aspirate) prior to use. OsteoFlo HydroFiber may be used as standalone, equivalent to autograft, in conjunction with autograft, or as a bone graft extender.

**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), OsteoFlo HydroFiber, SurGenTec (K242797)

**Technological Similarities and Differences:**
The subject device and primary predicate device are both resorbable bone void fillers that are intended for be placed in bony defects. The subject device and primary predicate differ in package formats and material composition. The performance testing that has been conducted demonstrates that these differences do not raise different questions of safety and effectiveness, further the results of the performance testing demonstrates substantial equivalence of the subject device to the 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 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
- Endotoxin validation testing per AAMI ST72
- Material characterization, including x-ray diffraction, particle size, and particle porosity and surface area
- Dimensional stability assessment
- *In vivo* evaluation in a Rabbit Metaphyseal Defect Model
- Pyrogenicity Testing

**Substantial Equivalence:**
Both the subject OsteroFlo® HydroFiber™ and predicate MASTERGRAFT® Putty are provided as a sterile, dry, solid, and mixed with sterile solution at the time of use to form a moldable bone void filler. The devices are applied as malleable putty. The binder 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 technical components and material compositions of the subject and predicate device differ, but these differences do not raise questions of safety and effectiveness, as demonstrated through the non-clinical testing. 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.