August 14, 2020

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

Re: K200064
Trade/Device Name: OsteoFlo® NanoPutty® - Quadphasic Synthetic Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 23, 2020
Received: July 24, 2020

Dear Mr. 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for

Laura C. Rose, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200064

Device Name
OsteoFlo® NanoPutty®- Quadphasic Synthetic Bone Graft

Indications for Use *(Describe)*
OsteoFlo® NanoPutty – Quadphasic Synthetic Bone Graft 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.

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.

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Premarket Notification 510(k) Summary

OsteoFlo NanoPutty Bone Void Filler - K200064

1. Submitter Information:

Owner:	SurGenTec, LLC
Address:	911 Clint Moore Rd Boca Raton, FL 33487
Contact:	Travis Greenhalgh, CEO
Telephone:	(916) 759-7999
Email:	travis@SurGenTec.com
Date Submitted:	December 9, 2019

2. Name of Device:

Trade Name:	OsteoFlo® NanoPutty® - Quadphasic Synthetic Bone Graft
Common Name:	Bone Void Filler
Classification Name:	Resorbable Calcium Salt Bone Void Filler
Device Regulation:	21 CFR 888.3045
Regulatory Class:	Class II
Product Code:	MQV

3. Legally Marketed Predicate Device:

Predicate: NovaBone Putty - Bioactive Synthetic Bone Graft
NovaBone Products, LLC
K110368, K101860, K082672

The following devices also are cited as reference devices within the submission:

- Bioactive Bone Graft Putty: K132071; Biostructures, LLC
- NovaBone MacroPor-Si+: K110925; NovaBone Products, LLC
- NanOss BVF-E: K081558; Pioneer Surgical Technology

4. Device Description

The OsteoFlo® NanoPutty® - Quadphasic Synthetic Bone Graft is an osteoconductive, non-hardening bone void filler. The device is comprised of macroporous calcium phosphate particulates in a bioresorbable polymer binder. The quadphasic particles are composed of HA, a-TCP, B-TCP and bioactive glass. The device also contains micro-sized HA particles. On implantation, the binder is resorbed and bone forms on and between the porous particles as they are gradually resorbed.

OsteoFlo® NanoPutty can be easily packed into osseous defects and adheres to bone surfaces. The device is ready to use, requiring no mixing before application. The single-use device is supplied sterile in multiple package formats.

5. Indications for Use

The OsteoFlo® NanoPutty® – Quadphasic Synthetic Bone Graft 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.

6. Technological Characteristics and Substantial Equivalence

OsteoFlo® NanoPutty – Quadphasic Synthetic Bone Graft is substantially equivalent to the predicate NovaBone Putty Bioactive Synthetic Graft. The devices have the same intended use and basic method of operation. The table below compares the indications and key technological attributes of the OsteoFlo NanoPutty device to the predicate.

Comparator	**New Device** OsteoFlo NanoPutty	**Predicate** NovaBone Putty [K110368]
Product Code; Common Name	Resorbable Calcium Salt Bone Void Filler Device (21 CFR 888.3045)	
Indications for Use	OsteoFlo® NanoPutty – Quadphasic Synthetic Bone Graft 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.	NovaBone Putty is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, posterolateral spine, and pelvis). 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.
Intended Use	Both devices are intended for use as bone void fillers for repair of defects in the skeletal system. The devices are intended to be resorbed during defect healing and replaced with new bone tissue.	
Mechanism of Operation	The device is applied as a pre-mixed putty. The synthetic binder is resorbed to expose quadphasic particles. The particles act as osteoconductive scaffolds for new bone formation as they are slowly resorbed	The device is applied as a pre-mixed putty. The synthetic binder is resorbed to expose bioactive glass particles. The particles act as osteoconductive scaffolds for new bone formation as they are slowly resorbed
Material Composition	Quadphasic macroporous calcium phosphate particulates in a bioresorbable polymer	Bioactive glass particles, 90-710 µm, in a bioresorbable polymer binder

Comparator	New Device OsteoFlo NanoPutty	Predicate NovaBone Putty [K110368]
	binder	
Sterility	Sterile; SAL 10^{-6}; E-beam radiation; Single-Use	Sterile, SAL 10^{-6}; γ radiation; Single-Use
Product Size	1.0 ml – 10 ml	2.5 ml – 15 ml

7. Performance Data

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 critical-size rabbit femoral defect model

The *in vivo* evaluation compared the performance of the device to the NovaBone Putty predicate. Evaluation of local biological effects and bone formation demonstrated performance substantially equivalent to the predicate, with no evidence of adverse events or device related failures.

8. Conclusion

The design characteristics of the OsteoFlo NanoPutty device do not raise different questions of safety and effectiveness. Non-clinical study data supports that the device is safe and effective. These data support that the OsteoFlo NanoPutty device is substantially equivalent to the predicate device.