September 25, 2024

NovaBone Products, LLC
℅ Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
268 Glen Place
Franklin Lakes, New Jersey 07417

Re: K242299
Trade/Device Name: NovaBone Putty – Bioactive 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: August 2, 2024
Received: August 2, 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: 2024.09.25 13:14:49 -04'00'

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.

510(k) Number *(if known)*
K242299

Device Name
NovaBone Putty - Bioactive Synthetic Bone Graft

Indications for Use *(Describe)*
NovaBone Putty - Bioactive Synthetic Bone Graft is indicated only 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, pelvis, and intervertebral disc space). 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. When used in intervertebral disc space, NovaBone Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

NovaBone Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

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.

NOVABONE®

510(k) Summary

Submitter
Ed Horton
VP – Regulatory/Quality
NovaBone Products, LLC
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Alachua, FL 32615

Correspondent
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Founder and CEO
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Date Prepared
August 2, 2024

Device

Trade Name	NovaBone Putty – Bioactive Synthetic Bone Graft
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	Prosidyan - Fibergraft™ BG Putty (K222276)
Secondary Predicate	NuVasive - Attrax Putty (K203714)
Reference Devices	NovaBone Putty – Bioactive Synthetic Bone Graft (K240404)
	NovaBone Putty – Bioactive Synthetic Bone Graft (K082672)

Device Description
NovaBone Putty – Bioactive Synthetic Bone Graft is an osteoconductive, bioactive, bone void filler device. It is composed of a calcium-phosphorus-sodium-silicate (Bioglass) particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles then are slowly absorbed and replaced by new bone tissue during the healing process. The mixed device is supplied sterile and is provided in a PETG tray, disposable plastic syringe, or a pre-filled cartridge delivery system (MIS delivery system).

Indications for Use Statement

NovaBone Putty - Bioactive Synthetic Bone Graft is indicated only 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, pelvis, and intervertebral disc space). 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. When used in intervertebral disc space, NovaBone Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

NovaBone Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Substantial Equivalence

This submission expands the device's indications for use to include use in the intervertebral disc space. The intended use is the same for subject and predicate devices, which are cleared for use in intervertebral disc space. There are differences in the device's material composition, but this does not raise different questions of safety and effectiveness. The effect of differences in material composition is addressed in the prior functional animal model performance.

This submission incorporates a minor change in technological characteristics of the NovaBone Putty composition used in the tray and syringe configurations; the NovaBone Putty MIS delivery system device is identical to K240404. The NovaBone Putty device is designed as an osteoconductive space-filling material to be gently packed into osseous defect sites and used as a non-structural scaffold for the body's natural healing and bone regeneration process. The device is intended to be used alone, or in combination with autogenous bone.

Performance

The subject devices have been previously cleared under K240404 and K082672, which serve as Reference Devices. These submissions are 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.