February 5, 2024

NovaBone Products, LLC
% David Gaisser
Consultant
Geyser Medical Consulting
10205 SW 2nd Place
Gainesville, Florida 32607

Re: K240404
Trade/Device Name: NovaBone Putty - Bioactive Synthetic Bone Graft (NB6600, NB6610, NB6615)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 9, 2024
Received: February 9, 2024

Dear David Gaisser:

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: 2024.03.05 10:00:37 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240404

Device Name

NovaBone Putty - Bioactive Synthetic Bone Graft (NB6600, NB6610, NB6615)

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, 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.

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.

510(k) Summary

Date: February 09, 2024

Applicant: Ed Horton, VP – Regulatory/Quality
NovaBone Products, LLC
13510 NW US Hwy 441
Alachua, FL 32615
Telephone: 386-462-7660
Email: ehorton@novabone.com

Correspondent: David M. Gaisser
Geyser Medical Consulting
10205 SW 2nd Place
Gainesville, FL 32607
Telephone: 352-332-7110
E-Mail: dmgaisser@gmail.com

Type of Submission: Special 510(k)
Device Name: NovaBone Putty – Bioactive Synthetic Bone Graft
Common Name: Bone Void Filler
Regulation: 21 CFR 888.3045 – Resorbable Calcium Salt Bone Void Filler

Classification: Class II
Product Code: MQV
Review Panel: Orthopedic

Primary Predicate: NovaBone Putty – Bioactive Synthetic Graft [K112773]
Additional Predicate: NovaBone Putty [K060728, K080009, K082672, K101860, K110368]

Indications for Use:

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, 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.

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.

Device Description:

NovaBone Putty 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 packaged in single-use containers in multiple formats.

The device modification of the current submission adds an attachable applicator tip to the NovaBone Putty pre-filled cartridge delivery system (MIS delivery system). The tip provides for more precise control of NovaBone Putty placement.

Technological Characteristics and Substantial Equivalence

The technological characteristics of the NovaBone Putty device are identical to the NovaBone Putty device cleared per K060728, K080009, K082672, K101860, K110368, and K112773. The 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 indications are the same as for the predicate. The device is intended to be used alone, or in combination with autogenous bone.

The subject and K112773 predicate are identical in materials and device characteristics. The NovaBone Putty device of this submission has been modified from that of the predicate solely in terms of the addition of an applicator tip to the device package; the device material itself and the MIS delivery system are unchanged. The device packaging in predicate K112773 consists of pre-filled polypropylene cartridges, which are attached to a delivery handle. The cartridges serve as a cannula to direct material placement. The applicator tip of the subject device can be used to refine device placement. The device action as a synthetic, inorganic, biocompatible, and osteoconductive scaffold into which new bone will grow is unchanged.

Performance Testing Summary:

Nonclinical evaluations of the modified device were performed to demonstrate equivalence to the predicate device. These tests included:

- Cytotoxicity testing per ISO 10993-5
- Bioburden evaluation per ISO 11137-1
- Bench tests for verification of system mechanical integrity

Clinical Data

Human clinical testing was not conducted or relied upon for determining substantial equivalence for this premarket notification.

Substantial Equivalence:

The NovaBone Putty device of this submission has the same design, materials, mode of action, manufacturing and sterilization processes, and technological characteristics as the predicate device. The design modification to include a new MIS applicator tip component does not result in a change in device intended use or raise new questions regarding device safety or effectiveness. The NovaBone Putty of this submission is substantially equivalent to the predicate device.