April 7, 2025

Biocomposites Ltd
% Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
38 True Harbour Way
West Islip, New York 11795

Re: K250521
Trade/Device Name: NanoBone® SBX Putty; NanoBone® QD
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: February 21, 2025
Received: February 21, 2025

Dear Dr. 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: 2025.04.07 09:07:50 -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)*
K250521

Device Name
NanoBone® SBX Putty; NanoBone® QD

Indications for Use *(Describe)*
NanoBone® SBX Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, NanoBone® SBX Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

NanoBone® QD is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® QD resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, NanoBone® QD 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.

Biocomposites®

510(k) Summary

Submitter
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Regulatory Affairs Director
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Date Prepared
February 21, 2025

Device

Trade Name	NanoBone® SBX Putty NanoBone® QD
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	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Devices	NanoBone® SBX Putty and NanoBone® QD (K190110)

Device Description
NanoBone® SBX Putty and NanoBone® QD consist of NanoBone® granulate embedded in an aqueous gel. NanoBone granulate consists of phase-pure non-sintered nanocrystalline osteoconductive hydroxyapatite (HA) embedded in a highly porous silica gel matrix. The high porosity of the product includes nano pores, micro pores, and macro pores. The interconnected and open porous structure of the macro pores of the NanoBone® is similar to human cancellous bone. NanoBone® SBX Putty does not set in-situ following implantation.

NanoBone® SBX material is supplied in two different style applicators. The NanoBone® SBX Putty is supplied in a sterile applicator with an attached plunger. NanoBone® QD is an alternate packaging of the NanoBone® SBX Putty. NanoBone® QD is supplied in a sterile cartridge with a separate sterile plunger.

Biocomposites®

Indications for Use Statement

NanoBone® SBX Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, NanoBone® SBX Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

NanoBone® QD is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® QD resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, NanoBone® QD must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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.

Performance

The subject devices have been previously cleared under K190110, which serves as a Reference Device. This submission is 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 intervertebral spine 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 disc space. 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, Biocomposites concludes that the device is substantially equivalent to the predicates.