April 23, 2019

ARTOSS GmbH
Walter Gerike, Ph.D.
Managing Partner
Friedrich-Barnewitz-Strasse 3
18119 Rostock, Germany

Re: K190110
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: January 21, 2019
Received: January 23, 2019

Dear Dr. Gerike:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K190110

Device Name
NanoBone® SBX PUTTY

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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K190110

Device Name
NanoBone® QD

Indications for Use *(Describe)*
NanoBone® QD Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine 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 Putty 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)

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510(k) Summary
[as required by 21 CFR 807.92(c)]

NanoBone® Bone Graft Substitute
NanoBone® SBX Putty
NanoBone® QD

510(k) 190110

DATE PREPARED:	18 March 2019
APPLICANT:	ARTOSS GmbH Friedrich-Barnewitz-Strasse 3 18119 Rostock, Germany Telephone: +49 (0) 381 5 43 45 - 701 Fax: +49 (0) 381 5 43 45 - 702
CONTACT:	Walter Gerike, PhD Managing Partner ARTOSS GmbH gerike@artoss.com
TRADE NAME:	NanoBone® bone graft substitutes • NanoBone® SBX Putty • NanoBone® QD
COMMON NAME:	Bone Void Filler
CLASSIFICATION REGULATION:	Resorbable calcium salt bone void filler 21 CFR 888.3045, Product Code MQV
DEVICE CLASS:	2
PANEL CODE:	Orthopedic / 888
PREDICATE DEVICE:	ARTOSS NanoBone® bone graft substitutes NanoBone® SBX Putty (K161351)
REFERENCE DEVICE:	APATECH Actifuse ABX E-Z-Fil Putty Bone Graft Substitute (K071206)

INTENDED USE/INDICATIONS FOR USE:

NanoBone® SBX Putty and NanoBone® QD have the same intended use and indications for use:

NanoBone® SBX Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine 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.

NanoBone® QD Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine 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 Putty resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION:

NanoBone® SBX Putty consists 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.

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

Name of Devices	**NanoBone® SBX Putty / NanoBone® QD**	**NanoBone® SBX Putty**	**Actifuse ABX Putty**
	Subject	Predicate	Reference
510(k)		K161351	K071206
Intended Use	Bone void filler	Bone void filler	Bone void filler
Target Location	Extremities, pelvis, spine	Extremities, pelvis	Extremities, pelvis, spine
Formulation	Putty	Putty	Putty
Material	Hydroxyapatite (HA) embedded in a silica gel matrix	Hydroxyapatite (HA) embedded in a silica gel matrix	Silicate substituted calcium phosphate (hydroxyapatite)
Carrier	Poloxamer	Poloxamer	Poloxamer
Granule Size	0.6mm x 2mm	0.6mm x 2mm	1mm-2mm
How Supplied	In applicators ranging in size from 0.25mL to 10 mL	In applicators ranging in size from 0.25mL to 10 mL	Pack size: 1.5mL to 20mL E-Z Prep applicator: 10 mL MIS cartridge: 7.5mL
Sterilization	Radiation	Radiation	Radiation

The NanoBone® SBX Putty/NanoBone® QD and the predicate and reference devices have the same intended use, to fill bony voids and gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or those created from traumatic injury to the bone.

The subject device was not been previously submitted for a posterolateral indication. The subject device and the predicate device have identical design and technological characteristics. NanoBone® SBX Putty/NanoBone® QD have the same indications, contraindications, risks, basic technology, equivalent materials, and potential adverse events as the NanoBone® predicate (K161351). The only difference between the predicate ARTOSS

NanoBone® bone graft substitute and the subject device is the addition of posterolateral fusion indication, and the addition of the alternate applicator.

NON-CLINICAL TESTING/PERFORMANCE DATA:

Previously submitted bench testing has shown the NanoBone® products meet all relevant requirements for calcium salt bone void filler devices, including ASTM F1185. Testing was performed on the predicate device to characterize and evaluate the performance of the NanoBone® products. The testing included:

- Chemical / elemental analysis
- Phase purity / XRD
- Dissolution testing
- Animal testing
- Biocompatibility assessment / testing
- Pyrogenicity
- Sterilization validation
- Shelf life

The *in vitro* bench tests demonstrated that the NanoBone® bone graft substitutes met all acceptance criteria and performed similarly to the predicate devices.

Additional animal testing was performed to show the performance for use in posterolateral fusion. Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate and reference devices.

BIOCOMPATIBILITY:

The NanoBone® bone graft substitutes were compared to the predicate and reference devices. Based on the use of identical materials in the subject device and predicates devices, the biocompatibility of the NanoBone® bone graft substitutes was verified to be the same as those of the predicates.

CONCLUSION:

The NanoBone® bone graft substitutes (NanoBone® SBX Putty and NanoBone® QD) have the same intended use and the same technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate. Performance data demonstrates that the device functions as intended.

Therefore, the NanoBone® SBX Putty and NanoBone® QD are substantially equivalent to the predicate devices.