DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 26, 2016

ARTOSS GmbH
Dr. Walter Gerike
Managing Partner
Friedrich-Barnewitz-Strasse 3
Rostock 18119
GERMANY

Re: K161351
Trade/Device Name: NanoBone® SBX Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 18, 2016
Received: September 20, 2016

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161351

Device Name
NanoBone® SBX Putty

Indications for Use *(Describe)*
NanoBone® SBX Putty is intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. NanoBone® SBX Putty is intended to be packed into bony voids or gaps of the skeletal system as a bone void filler (i.e., extremities and pelvis). This product provides a bone void filler that resorbs and is replaced by 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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510(k) Summary
(as required by 21 CFR 807.92)

NanoBone® SBX Putty

510(k) K161351

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Contact Person	Walter Gerike Managing Partner ARTOSS GmbH gerike@artoss.com
Date Prepared	10/25/2016

Trade Name	NanoBone® SBX Putty
Common Name	Bone Void Filler
Classification Regulation	Resorbable calcium salt bone void filler 21 CFR 888.3045, Product Code MQV
Class	Class II Special Controls
Panel code	Orthopedic / 888
Predicate Devices	ARTOSS NanoBone® granulate (K141189) ApaTech Actifuse™ ABX E-Z-fil (K071206)
Intended Use and Indications	NanoBone® SBX Putty is intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. NanoBone® SBX Putty is intended to be packed into bony voids or gaps of the skeletal system as a bone void filler (i.e., extremities and pelvis). This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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.
Technological Characteristics-Comparison to Predicate Devices	NanoBone® SBX Putty is composed of the same porous calcium phosphate as used in the NanoBone® predicate (K141189), with the same aqueous gel as the predicate Actifuse ABX E-Z-fil (K071206). The NanoBone® SBX Putty and the predicate NanoBone granulate (K141189) 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. NanoBone® SBX Putty has the same indications, contraindications, risks, basic technology, equivalent materials, and potential adverse events as the NanoBone® granulate predicate (K141189). The only difference between the predicate ARTOSS NanoBone® granulate and the Subject device is the addition of an aqueous carrier and primary packaging in an applicator. The Subject devices are therefore substantially equivalent to its predicates.
Performance Data	Bench testing has shown the NanoBone® SBX Putty meets the requirements of all relevant requirements for calcium salt bone void filler devices, including ASTM F1185. Testing was performed to characterize and evaluate the performance of the NanoBone® products. The testing included: • Chemical / elemental analysis • Phase purity / XRD • Dissolution testing • Biocompatibility assessment / testing • Sterilization validation • Pyrogenicity testing • Animal testing Performance testing was undertaken to demonstrate that NanoBone® SBX Putty is capable of healing a critically-sized defect in a clinically relevant implantation site. A well-established critical-sized femoral condyle defect model in the mature New Zealand white rabbit was used. Thirty rabbits were divided into two groups of fifteen. Test articles were implanted bilaterally in 5mm diameter and 10mm deep defects in the lateral aspect of the femoral condyles. Fifteen experimental defects were implanted with NanoBone® SBX Putty. Fifteen control defects were implanted with NanoBone® | granulate and another fifteen control defects were implanted with Actifuse® ABX Putty. Five rabbits from each group were sacrificed at 4, 8, and 12 weeks after implantation. The safety and performance of each test article were evaluated using histology, histomorphometry, micro CT, and image analysis. Outcome measures were new bone formation and product resorption. Based upon the results of this testing, NanoBone SBX Putty performs satisfactorily as a bone void filler and in a manner substantially equivalent to the predicates NanoBone | granulate (K141189) and Actifuse ABX Putty (K071206)

Conclusions	NanoBone® SBX Putty has the same intended use and similar technological characteristics as the predicate devices. Performance data demonstrates that the product performs as intended, and is substantially equivalent to its predicates.