DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 30, 2015

ARTOSS GmbH
Dr. Walter Gerike
Managing Partner
Friedrich-Barnewitz-Str.3
18119 Rostock
Germany

Re: K141189
Trade/Device Name: NanoBone® bone graft substitutes – NanoBone® | granulate
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 22, 2014
Received: January 7, 2015

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 Part 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 yours,

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)*
K141189

Device Name
NanoBone® bone graft substitutes
- NanoBone® | granulate

Indications for Use *(Describe)*

NanoBone® bone graft substitutes are intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure. NanoBone® bone graft substitutes are indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. NanoBone® bone graft substitutes are 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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NanoBone®

510(k) Summary

(as required by 21 CFR 807.92)

NanoBone® bone graft substitutes
NanoBone® | granulate

510(k) K141189

Submitter	ARTOSS GmbH Friedrich-Barnewitz-Staβe 3 18119 Rostock, Germany Telephone: +49 (0) 381 5 43 45 - 701 Fax: +49 (0) 381 5 43 45 - 702

Contact Person	Walter Gerike Managing Partner ARTOSS GmbH gerike@artoss.com

Date Prepared	28 January 2015

Trade Name	NanoBone® | granulate
Common Name	Bone Void Filler
Classification Name	Resorbable calcium salt bone void filler (21 CFR 888.3045, Product Code MQV)
Class	Class II

Predicate Devices	Actifuse™ Bone Graft Substitute, K040082, K082575 NovaBone, NovaBone AR, K060432, K041613

Intended Use	NanoBone® bone graft substitutes are intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure. NanoBone® bone graft substitutes are indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. NanoBone® bone graft substitutes are 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 consists of phase-pure non-sintered nanocrystalline osteoconductive hydroxylapatite (HA) embedded in a highly porous silica gel matrix. The interconnected and open porous structure of NanoBone is similar to human cancellous bone. NanoBone is available as an irregular granulate.

Technological Characteristics - Comparison to Predicate Devices	The NanoBone and its predicates 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. All forms of the NanoBone material have the same the same indications, contraindications, risks and potential adverse events as the predicate devices. The NanoBone products have the same basic technologies and are composed of equivalent materials.

Performance Data	Bench testing has shown the NanoBone products meet the requirements of all relevant requirements for Calcium Salt Bone Void Fillers, including ASTM F1185. Additional testing was performed to characterize and evaluate the performance of the NanoBone products. This testing included: • Chemical / elemental analysis • Phase purity / XRD • Dissolution testing • Animal testing • Biocompatibility testing • Sterilization validation

	Animal testing was performed to demonstrate substantial equivalence including determination of radiographic, histologic and histomorphometric characteristics of the subject device and the controls in a critical-sized defect model in the sheep tibia. The study time points included 6 weeks, 12 weeks, and 26 weeks. Autograft bone filled defects (positive control) and empty unfilled defects (negative control) also were evaluated at these same time points.

Conclusion	The NanoBone® | granulate 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.