DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 21, 2015

TCM Associates Ltd
Mr. Iain Alligan
Technical Director
3 Hillgrove Business Park
Nazeing Road
Essex EN9 2HB United Kingdom

Re: K143692
Trade/Device Name: GranOS - beta tricalcium phosphate synthetic bone granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: July 13, 2015
Received: July 23, 2015

Dear Mr. Alligan:

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" (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 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)*
K143692

Device Name
GranOS™ - beta tricalcium phosphate synthetic bone granules

Indications for Use *(Describe)*

GranOS™ devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GranOS™ is indicated to be gently placed into bony voids or gaps of the skeletal system (ie 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

Premarket Notification 510(k) Summary

beta tricalcium phosphate synthetic bone granules (Trade Name: GranOS™)

5.1 Premarket Notification 510(k) Summary

GranOS™ - beta tricalcium phosphate synthetic bone granules
(per 21 CFR 807.92)

Submitter (Owner)
TCM Associates Ltd
3 Hillgrove Business Park
Nazeing Road
Nazeing
Essex
EN9 2HB
United Kingdom

Contact Person
Iain Alligan , Technical Director
Phone: +44 (0) 1992 892 085
Fax: +44 (0) 1992 893 721

Date prepared
20th August 2015

Trade Name
GranOS™ - beta tricalcium phosphate synthetic bone granules

Common Name
Synthetic bone void filler

Device Classification
Resorbable calcium salt bone void filler device

Regulation
Class II Special Controls as per 21 CFR 888.3045

Device Product Code
MQV

Legally Marketed Predicate Devices
βGran® Synthetic Osteoconductive Scaffold (K041616)
Cerasorb® ORTHO (K014156)
Vitoss ® Scaffold Synthetic Cancellous Bone Void Filler K032409

Device Description
GranOS™ is a porous, resorbable osteoconductive scaffold constructed of highly pure beta tricalcium phosphate granules for use in the repair of bony defects.

Intended Use
GranOS™ devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GranOS™ is indicated to be gently placed 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

Technological Characteristics - Comparison to Predicates and Substantial Equivalence

Trade Name	**GranOS™ - beta tricalcium phosphate synthetic bone granules**	**βGran® synthetic osteoconductive scaffold**	**Cerasorb® ORTHO**	**Vitoss® Scaffold Synthetic Cancellous Bone void Filler**
510(k) Registration No:	**K143692**	**K041616**	**K014156**	**K032409**
Chemical composition of the material	beta tricalcium phosphate $Ca_3(PO_4)_2$ meeting the requirements of ASTM F 1088-04a (2010)	beta tricalcium phosphate $Ca_3(PO_4)_2$ meeting the requirements of ASTM F 1088-04a (2010)	beta tricalcium phosphate $Ca_3(PO_4)_2$ meeting the requirements of ASTM F 1088-04a (2010)	beta tricalcium phosphate $Ca_3(PO_4)_2$ meeting the requirements of ASTM F 1088-04a (2010)
Patient Population	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma	Patients with bone voids or gaps caused by surgery trauma or degeneration	Individuals with bony defects resulting from surgery or trauma
Anatomical Locations	To be packed into the irregular shaped bony voids of the skeletal system i.e. extremities, spine and pelvis	Bony voids or gaps of the skeletal system i.e. the extremities, spine and pelvis	Skeletal system extremities, spine and pelvis	Bony voids or gaps of the skeletal system i.e. the extremities, spine and pelvis
Physical Structure of the Material	Interconnected porosity	Interconnected porosity	Interconnected porosity	Trabecular structure similar to cancellous bone
Porosity	Approximately 70%	Approximately 70%	Approximately 60% - 70%	Approximately 90%
Pore Size (range)	Micropores <1 - 700µm	Micropores <1 - 700µm	Micropores >0<80 µm	1-1000 µm
Performance Osteoconductivity	Osteoconductive	Osteoconductive	Osteoconductive	Osteoconductive
Sterility	Sterilised by Gamma Radiation, single use only. Sterility Assurance Level (SAL) of 1 x 10^{-6}	Sterilised by Gamma Radiation, single use only. Sterility Assurance Level (SAL) of 1 x 10^{-6}	Sterilised by Gamma Radiation, single use only. Sterility Assurance Level (SAL) of 1 x 10^{-6}	Sterilised by Gamma Radiation, single use only. Sterility Assurance Level (SAL) of 1 x 10^{-6}
Biocompatibility	Established	Established	Established	Established
Presentation	Granule Sizes 250-500µm 1 – 2.8mm 2 – 4mm	Granule Sizes 250-500µm 1 – 2.8mm 2 – 4mm	Granules and Blocks 500 - 1000µm 1000 - 2000µm	Morsels 1-4mm and cylinders 9 x 23mm

Results of non-clinical performance tests has demonstrated that GranOS™ - beta tricalcium phosphate granules have the same critical specification (i.e. chemistry, crystallinity, physical form, porosity, dissolution/solubility) and the same intended use as the predicate device.

Key requirements and recommendations have also been met within The Class II Special Controls Guidance: Document Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.

Non-clinical testing

GranOS™ - beta tricalcium phosphate granules have been tested and shown to be in compliance to the following recognised performance standard: ASTM F1088-04a 2010 - Standard Specification for beta tricalcium phosphate for Surgical Implantation. In addition, GranOS™ - beta tricalcium phosphate granules have the same Contraindications, Instructions, Warnings, Precautions and possible adverse reactions/complications when directly compared to the predicate devices and so does not raise new questions regarding safety and effectiveness and therefore substantial equivalence is claimed under Section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)).

[21CFR 807.92(b)(1) and 21CFR 807.92(b)(2])

Conclusion

Based on the results of the non-clinical testing and the data gathered from the clinical evaluation of the product, we conclude that GranOS™ - beta tricalcium phosphate granules are as safe, as effective, and performs as well as or better than the predicate device.

[21CFR 807.92(b)(3)