DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 18, 2017

OsteoNovus, Inc.
% Kevin A. Thomas, Ph.D.
Vice President and Director of Regulatory Affairs
Paxmed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K162087
Trade/Device Name: NovoGro
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, 2017
Received: February 22, 2017

Dear Dr. Thomas:

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,

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)*

K162087

Device Name

NovoGro

Indications for Use *(Describe)*

NovoGro Putty is intended for use as a bone void filler for gaps and voids that are not intrinsic to the stability of the bony structure. NovoGro Putty is intended to be hydrated with sterile water and gently packed into bony voids or gaps of the skeletal system, i.e., extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovoGro Putty 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

OsteoNovus, Inc.

NovoGro

February 21, 2017

ADMINISTRATIVE INFORMATION

Manufacturer Name	OsteoNovus, Inc. 1510 North Westwood Avenue, Suite 1080 Toledo, OH 43606 Telephone: +1-617-717-8867
Official Contact	Brian M. Schlossberg, PhD Director of Research and Development
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1-858-792-1235 Fax: +1-858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	NovoGro
Common Name	Filler, bone void, calcium compound
Classification Name	Resorbable calcium salt bone void filler device
Classification Regulations	21 CFR 888.3045, Class II
Product Code	MQV
Classification Panel	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch	Restorative and Repair Devices Branch (RRDB)

PREDICATE DEVICE INFORMATION

The primary predicate device is K071206, Actifuse ™ ABX E-Z-fil Bone Graft Substitute, ApaTech Limited.

INDICATIONS FOR USE

NovoGro Putty is intended for use as a bone void filler for gaps and voids that are not intrinsic to the stability of the bony structure. NovoGro Putty is intended to be hydrated with sterile water and gently packed into bony voids or gaps of the skeletal system, i.e., extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovoGro Putty provides a bone void filler that resorbs and is replaced by bone during the healing process.

SUBJECT DEVICE DESCRIPTION

NovoGro Putty is provided to the end-user as two components (dry powder and aqueous solution) that must be mixed intra-operatively prior to implantation using the supplied mixing system to form a moldable cohesive putty-like graft. The dry powder component of NovoGro Putty contains spherical beads that are composed primarily of a co-precipitate of dicalcium phosphate anhydrite [monetite, $CaHPO_4$], magnesium phosphate trihydrate [newberyite, $Mg(PO_3OH)•3(H_2O)$] and sodium hydrogen phosphate [NaH_2PO_4]. Small amounts of silica (SiO_2) and magnesium oxide (MgO) are combined with this co-precipitate during manufacturing. These spherical beads are mixed heterogeneously with dry sodium carboxymethyl cellulose (CMC) powder to enhance the handling properties of the final mixed graft. The aqueous component of NovoGro is ultrapure reverse osmosis deionized water (DI H_2O). NovoGro Putty is provided sterile for single use in volumes ranging from 1 cc to 20 cc. NovoGro Putty is provided in a kit with a mixing system, a vial of ultrapure water for mixing, and a graduated syringe to measure the correct volume of the supplied ultrapure water to add to the dry component.

PERFORMANCE DATA

Pre-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, and performance characteristics.

Chemical characterization of the subject device included identification and quantification of crystalline and non-crystalline components using powder x-ray diffraction (PXRD) and Fourier transform infrared spectroscopy (FTIR), and elemental composition analysis (including heavy metal content) using ion coupled plasma mass spectrometry (ICP-MS). Calcium dissolution and pH measurement testing were performed for the subject device NovoGro Putty and the predicate device Actifuse ABX. Chemical characterization was performed using methods described in ASTM F2024, ASTM F1185, and ASTM F1926/F1926M.

Physical characterization of the subject device included scanning electron microscopy (SEM); particle size distribution; device mass, volume, and density by gas displacement pycnometry; surface area by gas adsorption; and device porosity by mercury intrusion porosimetry.

Biocompatibility testing was performed using methods described in AAMI/ANSI/ISO 10993-1, ISO 10993-3, AAMI/ANSI/ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, and ISO 10993-18. Material mediated pyrogenicity testing and bacterial endotoxin testing were performed using the using methods described in ISO 10993-11 and AAMI/ANSI ST72, respectively.

Sterilization validation, sterile barrier shelf life, and product shelf life testing were performed according to AAMI/ANSI/ISO 11137-1, AAMI/ANSI/ISO 11137-2, ASTM D4169, ASTM F1980, ASTM F1886/F1886M, ASTM F2096, and ASTM F88/F88M.

Animal testing performed to demonstrate substantial equivalence included determination of radiographic, histologic and histomorphometric characteristics of the subject device and the predicate device in a rabbit distal femoral condyle critical-sized defect model. The study time points included baseline (time 0), 6 weeks, and 12 weeks. The baseline (time 0) animals provided information on the initial amount of material implanted to fill the defects. Empty (unfilled) defects (negative control) were evaluated at 6 weeks and 12 weeks. Evaluation endpoints included high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis. Histology sections also were graded according to AAMI/ANSI/ISO 10993-6 (Annex E).

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

OsteoNovus, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the legally marketed predicate device, Actifuse ™ ABX E-Z-fil Bone Graft Substitute, ApaTech Limited, K071206.

A comparison of the technological characteristics of the subject device and the predicate device K071206 is provided in the following table.

Comparison	**Subject Device** OsteoNovus, Inc. NovoGro	**Predicate Device** ApaTech Limited Actifuse ™ ABX E-Z-fil Bone Graft Substitute K071206
Indications for Use	NovoGro Putty is intended for use as a bone void filler for gaps and voids that are not intrinsic to the stability of the bony structure. NovoGro Putty is intended to be hydrated with sterile water and gently packed into bony voids or gaps of the skeletal system, i.e., extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovoGro Putty provides a bone void filler that resorbs and is replaced by bone during the healing process.	Actifuse is a bone void filler intended only for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral fusion procedures with appropriate stabilizing hardware. 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 by bone during the healing process.
Product Code	MQV	MQV
Intended Use	Bone void filler for skeletal system (extremities, pelvis)	Bone void filler for skeletal system (extremities, pelvis) and posterolateral spine
Design		
Form	NovoGro Putty: Regularly shaped granules premixed with a soluble polymeric binder	Irregularly shaped granules premixed with a soluble aqueous gel carrier
Granule Size	1 – 2 mm (1000 – 2000 μm)	1 – 2 mm (1000 – 2000 μm)
Porosity	NovoGro Putty: 31.3%	20 %
Materials		
Calcium salts	monetite / newberyite / sodium hydrogen phosphate [$CaHPO_4$ + $Mg(PO_3OH)•3(H_2O)$ + NaH_2PO_4]	Hydroxyapatite (HA)
Silicon	NovoGro Putty: 14% by weight	0.8 % by weight
Scaffold/Binder	Sodium carboxymethyl cellulose (CMC)	Aqueous gel carrier (resorbable polymer, not specified)
How Supplied		
Sizes, shapes	Provided in delivery/mixing syringe Final graft volumes ranging from 1 cc – 20 cc	Provided in delivery syringe Volumes ranging from 1.5 mL to 20 mL
Single use	Yes	Yes
Sterile	Yes	Yes
Sterilization	Gamma irradiation	E-beam irradiation

The subject device and the predicate device have the same intended use, the same product classification and product code (MQV), and have similar indications for use. The subject device and predicate device are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure (extremities and pelvis); the predicate device has an additional indication for use in the posterolateral spine. Although the subject device and the predicate have slightly different Indications for Use language, this difference in language does not change the intended use as a bone void filler in the extremities and pelvis.

The subject device and the predicate device both incorporate calcium phosphate materials, Si, and a polymeric scaffold or binder. NovoGro Putty contains approximately 14% Si by weight and the predicate Actifuse ABX contains approximately 0.8% Si by weight. The subject device and the predicate device have the same range of granule size (1 mm - 2 mm), and have similar porosities. The subject device and the predicate device are provided sterile for single use in similar ranges of graft volumes.

The radiographic, histologic and histomorphometric performance of the subject device was compared to that of the predicate device in a rabbit distal femoral condyle critical-sized defect model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the predicate Actifuse ABX device.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate device listed above.