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

April 6, 2018

Re: K173525
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: March 8, 2018
Received: March 9, 2018

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.

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.

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,

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)*

K173525

Device Name

NovoGro

Indications for Use *(Describe)*

NovoGro Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). NovoGro must be used with autograft as a bone extender in the posterolateral spine. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device 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."

510(k) Summary
K173525
NovoGro
OsteoNovus, Inc.

April 5, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name	OsteoNovus, Inc. 1510 North Westwood Avenue, Suite 2040 Toledo, OH 43606 Telephone: +1-419-530-5940 Fax +1-419-530-5932
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 K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc. The reference predicate device is K162087, NovoGro, OsteoNovus, Inc.

INDICATIONS FOR USE

NovoGro Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). NovoGro must be used with autograft as a bone extender in the posterolateral spine. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device resorbs and is replaced with 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 particles 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 particles 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, and 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 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 posterolateral spine fusion model. Animals implanted with autograft (positive control) also were evaluated. The study time points included baseline (time 0), 6 weeks, 9 weeks, and 12 weeks. Evaluation endpoints included manual palpation, range of motion/flexibility testing, plain and 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.

Bioactivity testing included an in vitro study comparing the subject device NovoGro Putty, positive control (bioactive glass), and negative control (polyethylene) in the presence of simulated body fluid. Apatitic calcium phosphate formation was observed on surface of the NovoGro Putty and a positive

control, but not on the surface of the negative control. Bioactivity has not been evaluated in human clinical trials.

EQUIVALENCE TO MARKETED DEVICE

OsteoNovus, Inc. submits the 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 devices, K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc., and K162087, NovoGro, OsteoNovus, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K140375 is provided in the following table.

Comparison	**Subject Device** K173525 NovoGro OsteoNovus, Inc.	**Primary Predicate Device** K140375 MASTERGRAFT® Strip; MASTERGRAFT® Putty Medtronic Sofamor Danek USA, Inc.
Indications for Use	NovoGro Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). NovoGro must be used with autograft as a bone extender in the posterolateral spine. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device resorbs and is replaced with bone during the healing process.	MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.
Product Code	MQV	MQV
Intended Use	Bone void filler for skeletal system (posterolateral spine, extremities, pelvis)	Bone void filler for skeletal system (posterolateral spine, extremities, pelvis)
Use in Spine	Mixed with autograft (required)	Mixed with autograft (optional)
Design		
Form	Regularly shaped granules premixed with a soluble polymeric binder	Granules uniformly dispersed in collagen scaffold
Granule Size	1 – 2 mm (1000 – 2000 µm)	0.5 mm – 1.6 mm in diameter
Porosity	31.3%	Granules 80%
Materials		
Calcium salts	monetite / newberyite / sodium hydrogen phosphate [$CaHPO_4$ + $Mg(PO_3OH)•3(H_2O)$ + NaH_2PO_4]	β-tricalcium phosphate (85%) and Hydroxyapatite (15%)
Silicon	NovoGro Putty: 14% by weight	Not applicable
Scaffold/Binder	Sodium carboxymethyl cellulose (CMC)	Type I bovine collagen
How Supplied		
Sizes, shapes	Provided in delivery/mixing syringe Final graft volumes ranging from 1 cc – 20 cc	Provided in 0.75 cc, 1.5 cc, 3.0 cc, 6.0 cc, and 9.0 cc packages
Sterility	Provided sterile to end-user	Provided sterile to end-user
Sterilization	Gamma irradiation	Not stated
Usage	Single-patient, single-use	Single-patient, single-use

The primary predicate device is K140375 for substantial equivalence in the animal model performance testing. The reference predicate device is K162087 for support of substantial equivalence in terms of the device material composition and physical form.

The subject device and the primary predicate device have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use statements. The subject device and the primary predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure. The subject device and primary predicate device are indicated for use in the posterolateral spine with autograft bone (extender). Although the subject device and the primary 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 posterolateral spine.

The subject device and the primary predicate device each incorporate calcium phosphate materials within a polymeric binder or scaffold. The subject device polymeric binder is sodium carboxymethyl cellulose (CMC), and the primary predicate K140375 scaffold is type I bovine collagen. The subject device and the reference predicate device are identical in material composition and physical form. The subject device and the predicate devices are provided sterile for single-patient, single-use in similar ranges of graft volumes.

The subject device and the reference predicate device K162087 are the same except for the indications for use. The subject device is not to be hydrated after mixing of the dry powder component with the ultrapure water, the primary predicate K140375 is to be hydrated with bone marrow aspirate and/or sterile water prior to use. In the posterolateral spine the subject device must be mixed with autograft bone, whereas the primary predicate device may be used without or with autograft bone.

The radiographic, histologic, and histomorphometric performance of the subject device were compared to that of the primary predicate device K140375 in a rabbit posterolateral fusion model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the predicate device K140375.

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 device and the predicate devices are provided sterile for single-patient, single-use in similar ranges of graft volumes, and 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.