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 18, 2017

NovaBone Products, LLC
% Ms. Lisa C. Simpson
Consultant
Simpson Regulatory Solutions, LLC
4401 NW 18th Place
Gainesville, Florida 32605

Re: K163310
Trade/Device Name: NovaBone IRM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 21, 2016
Received: November 23, 2016

Dear Ms. Simpson:

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)*
K163310

Device Name
NovaBone IRM

Indications for Use *(Describe)*

NovaBone IRM – Bioactive Synthetic Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone IRM (Irrigation Resistant Matrix) is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities 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.

510(k) Summary of Safety & Effectiveness

Date Prepared: November 19, 2016

510(k) Holder / Submitter:

NovaBone Products, LLC
13510 NW US Highway 441
Alachua, FL 32615

Contact: Gregory Pomrink
Director, R&D and RA
Ph: (386) 518-6973 / Fax: (386) 462-7525
Email: gpomrink@novabone.com

Regulatory Contact:

Simpson Regulatory Solutions, LLC
4401 NW 18 Place
Gainesville, FL 32605

Contact: Lisa C. Simpson
Email: regulatorysolutions@icloud.com
Ph: (352) 562-5122

Name of Device:

Trade Names:	NovaBone IRM
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 888.3045 Regulation Name: Bone Void Filler
Regulatory Class:	Class II
Product Code:	MQV

Legally Marketed Predicate Devices:

K112773[1]	NovaBone Putty MIS (primary predicate)
K141207	NovaBone Bioactive Strip (reference predicate)

[1] FDA clearances for NovaBone Putty product line also include K060728, K080009, K082672, K101860, K110368, and K112773, which represent various packaging formats and indications for use changes.

510(k) Summary of Safety & Effectiveness

Device Description

NovaBone IRM is an osteoconductive bioactive device used for grafting osseous defects. It is a premixed composite of bioactive calcium-phospho-silicate particulate and a synthetic, absorbable binder. The bioactive particulate is composed solely of elements that exist naturally in normal bone (Ca, P, Na, Si, O). The device requires no mixing or preparation prior to application. NovaBone IRM is supplied ready-to-use, to be applied directly to the intended graft site. The binder is then absorbed from the site such that only the bioactive particulate remains.

Upon absorption of the binder, the remaining particulate material undergoes a time-dependent kinetic modification of the surface that occurs when implanted in living tissue. Specifically, a series of surface reactions results in the formation of a calcium phosphate layer on the particles that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow, allowing complete repair of the defect. Animal testing has demonstrated that the majority of the particulate material is absorbed within six months of implantation, with >98% of the material being absorbed by twelve months. The timeframe for full absorption in humans has not been determined, but is expected to be at least twelve months.

Indications for Use

NovaBone IRM – Bioactive Synthetic Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone IRM (Irrigation Resistant Matrix) is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities 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 and Substantial Equivalence

The proposed NovaBone IRM device is substantially equivalent to the primary predicate, NovaBone Putty (K112773). Both devices incorporate 45S5 bioactive glass in a synthetic binder that facilitates handling and are used as bone void fillers in the extremities and pelvis. The bioglass particles sizes for the proposed device are the same as the reference predicate, NovaBone Bioactive Strip (K141207). The packaging formats for NovaBone IRM are equivalent to that of NovaBone Putty (K112773). A biocompatibility assessment for NovaBone IRM supports safety of the device for implantation in bone voids. The results of a rabbit femoral defect model further support biocompatibility and show the device performance to be substantially equivalent to NovaBone Putty (K112773) for filling of osseous defects.

Conclusion

The composite of descriptive information, biocompatibility data, functional *in vivo* results in the rabbit model demonstrate that the safety and performance of NovaBone IRM is substantially equivalent NovaBone Putty (K112773), when used as a bone void filler in the extremities and pelvis per the defined indications for use.