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

August 26, 2015

Novabone Products, LLC
% Ms. Lisa Simpson
Consultant
Simpson Regulatory Solutions, LLC
4401 North West 18th Place
Gainesville, Florida 32605

Re: K152071
Trade/Device Name: NovaBone MacroFORM BIOACTIVE MIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 24, 2015
Received: July 27, 2015

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 on last page.*

510(k) Number *(if known)*

<to be determined>

Device Name

NovaBone MacroFORM BIOACTIVE MIS

Indications for Use *(Describe)*

NovaBone MacroFORM bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroFORM 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. NovaBone MacroFORM must be hydrated with autogenous bone marrow prior to implantation. 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**510(k) Summary of Safety & Effectiveness**

**Date Prepared:** July 24, 2015

**510(k) Holder / Submitter:**

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

Contact: Richard A. Davis
Director of Eng/RA/QA
Ph: (386) 462-1010 / Fax: (386) 462-7525
Email: rdavis@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 MacroFORM BIOACTIVE MIS |
| 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:**

| | |
|---|---|
| K140946 | NovaBone MacroFORM BIOACTIVE (primary predicate) |
| K112773 | NovaBone Putty MIS (reference predicate) |

**510(k) Summary of Safety & Effectiveness**

**Device Description**

NovaBone MacroFORM is an osteoconductive bioactive device used for grafting osseous defects. It is a composite of bioactive calcium-phospho-silicate granules and a collagen binder. The bioactive particulate is composed solely of elements that exist in normal bone (Ca, P, Na, Si, O). The collagen binder consists of bovine collagen. When mixed with bone marrow aspirate, the device forms a non-hardening graft that is applied directly to the intended graft site.

During absorption of the collagen binder, the particulate material remaining undergoes a time-dependent kinetic modification of the surface to stimulate osteoblast activity and guide the formation of bone across the graft site. Specifically, a series of surface reactions on the particles results in the formation of a calcium phosphate layer 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. During healing, the graft particulate is absorbed and remodeled into new bone.

MacroFORM BIOACTIVE MIS is provided in an MIS Cartridge (tube) for delivery using the NovaBone MIS Cartridge Handle accessory, supplied separately. The graft formulation is identical to MacroFORM BIOACTIVE moldable composite (K140946, primary predicate). The MIS Cartridge/Handle system is equivalent to that of NovaBone Putty MIS (K112773, reference predicate).

**Intended Use**

NovaBone MacroFORM devices are intended for prescription use only, to fill bony defects in the skeletal system. The device will be marketed with the following indications statement, which is identical to that of the primary predicate, MacroFORM BIOACTIVE moldable composite (K140946). Therefore, no new issues of safety or effectiveness are presented when MacroFORM BIOACTIVE MIS is used for the following indications, as labeled:

Indications for Use:

NovaBone MacroFORM bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroFORM 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. NovaBone MacroFORM must be hydrated with autogenous bone marrow prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

**510(k) Summary of Safety & Effectiveness**

**Technological Characteristics and Substantial Equivalence**

MacroFORM BIOACTIVE MIS and the predicate device utilize biocompatible materials that fill bony voids and provide an environment for bone regeneration. The host bone remodels through an osteoconductive process as new bone grows into the porous matrix of the graft materials. The graft materials are slowly resorbed and replaced by the host bone. The proposed and predicate devices are not intended to be load bearing and are only intended for use in defects that are not intrinsic to the stability of the bony structure. MacroFORM MIS and the predicate devices have the same mode of action and therefore no new issues of safety or effectiveness are presented.

MacroFORM BIOACTIVE MIS and the primary predicate (MacroFORM BIOACTIVE moldable composite, K140946) have the same graft formulation. Both devices incorporate the bioactive component, a three-dimensional porous structure comprised of Bioglass® 45S5, an inorganic calcium phospho-silicate, which conforms to ASTM F1538-03. The bioglass particles are compressed and heated to form a porous mass. Likewise, the bovine collagen used for the production of MacroFORM BIOACTIVE MIS is the same as that used for the primary predicate. The collagen is obtained from a single source in Australia, which is recognized by the World Organization for Animal Health (OIE) to be free of BSE and other similar TSE pathogens. Australia also is termed a Geographical BSE Risk I, or GBR I country. The GBR I designation is the lowest risk rating, indicating the potential for one or more animals to infected with BSE agents as "Highly Unlikely". The processing steps used for the bovine collagen constituent for MacroFORM have viral inactivation benefits. Because the device formulations and collagen sources are identical, no new issues of safety or effectiveness are presented.

The primary packaging differs for the MacroFORM BIOACTIVE MIS as compared to the MacroFORM primary predicate device (K140946). Biocompatibility (cytotoxicity, genotoxicity and intracutaneous irritation) testing passed for the graft in the new MIS Cartridge (tube) format. Therefore, no new issues of biocompatibility safety are presented by the packaging change.

The MacroFORM predicate device is hydrated with bone marrow aspirate (BMA) in a tray whereas the MIS version is hydrated in the MIS Cartridge (tube). A hydration study was conducted to evaluate the amount of fluid needed to sufficiently hydrate the graft and identify the optimal setting time prior to extrusion. Test devices were prepared using various fluid amounts and setting times, and then evaluated for hydration, handling, and immersion resistance. The instructions for use were updated based on this testing. Therefore, no new issues of safety or effectiveness are presented by hydration of MacroFORM in the MIS Cartridge.

The accessory Handle used for MacroFORM BIOACTIVE MIS is identical to that of the reference predicate, K112773, NovaBone Putty MIS. Only the packaging graphics have been changed. The packaging materials and sterilization method are unchanged relative

**510(k) Summary of Safety & Effectiveness**

to the reference predicate. Therefore, there are no new issues of safety or effectiveness for the MIS Handle accessory are presented.

Like the predicates, MacroFORM BIOACTIVE MIS devices are supplied sterile for single use. The predicate and proposed devices are sterilized to a sterility assurance level (SAL) of $10^{-6}$ using an irradiation method. Therefore, no new issues of safety or effectiveness are presented for MacroFORM BIOACTIVE MIS as compared to the primary and reference predicate devices.

**Conclusion**

The proposed NovaBone MacroFORM BIOACTIVE Moldable Composite MIS device system is substantially equivalent to the primary predicate MacroFORM BIOACTIVE (moldable composite, K140946. The indications for use and graft formulation are identical to the primary predicate. The only difference is the MIS version of MacroFORM BIOACTIVE is provided in Cartridge (tube) packaging, equivalent to the reference predicate, NovaBone Putty MIS (K112773). The MIS Handle accessory device is unchanged relative to the reference predicate. The potential risks associated with the packaging modifications have been identified and properly mitigated as supported by biocompatibility testing and a hydration study.

The information provided for this premarket notification supports substantial equivalence of MacroFORM BIOACTIVE MIS to the primary predicate device, MacroFORM BIOACTIVE moldable composite (K140946), with reference to NovaBone Putty MIS (K112773) for the MIS Cartridge/Handle system.

Therefore, NovaBone MacroFORM BIOACTIVE MIS is substantially equivalent to NovaBone MacroFORM BIOACTIVE moldable composite (K140946) when used for the same indications for use, to fill bony defects.