NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

OCT 14 2011

K112773 Pg 1/2

Special 510(k): Device Modification Summary
NovaBone Putty – Bioactive Synthetic Bone Graft

09/22/11

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13631 Progress Boulevard, #600 Alachua, FL 32615
Telephone:	(386) 462-7661
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Putty – Bioactive Synthetic Bone Graft
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 888.3045
Regulation Name:	Bone Void Filler

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone Putty – Bioactive Synthetic Graft [K060728, K080009, K082672, K101860, K110368]

4. Device Description

NovaBone Putty is an osteoconductive, bioactive, bone void filler device. It is composed of a calcium-phosphorus-sodium-silicate (Bioglass) particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles then are slowly absorbed and replaced by new bone tissue during the healing process. The mixed device is supplied sterile and is packaged in single-use containers in multiple formats.

The device modification of the current submission packages the device in pre-filled cartridges that are interchangeably attached to a dispensing handle. The length of the cartridges provides direct access application of the Putty to more remote defect sites.

5. Intended Use

NovaBone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed 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.

NovaBone Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

6. Technological Characteristics and Substantial Equivalence

The technological characteristics of the NovaBone Putty device are identical to the NovaBone Putty device cleared per K060728, K080009, K082672, K101860, and K110368. The device is designed as an osteoconductive space-filling device to be gently packed into defect sites and used as a non-structural scaffold for the body's natural healing and bone regeneration process. The device indications are the same as for the predicate. The device is intended to be used alone, or in combination with autogenous bone.

The primary component of NovaBone Putty is bioactive glass (45S5 Bioglass) particulate. This synthetic material is both biocompatible and osteoconductive. The NovaBone Putty includes a synthetic binder as an inert carrier for ease of handling and delivery, forming a premixed cohesive material. The binder is biocompatible and is absorbed after implantation, opening space between the bioactive glass particles for cell infiltration and bone formation. The bioactive glass particulate remains for a longer post-implantation period, acting as a scaffold for bone ingrowth. This particulate is absorbed and replaced by new bone tissue. Animal testing has demonstrated that the majority of the material is absorbed within six months of implantation, with >98% of the material being absorbed by 12 months. The timeframe for full absorption in humans has not been determined, but is expected to be at least 12 months.

The NovaBone Putty device of this submission has been modified from that of the predicate solely in terms of the device packaging; the device material itself is unchanged. The device packaging in predicate K101860 consists of a pre-filled polypropylene syringe to which a supplied cannula is attached to extend access to more remote graft sites. The current submission consists of a long, pre-filled polypropylene cartridge, which is attached to a delivery handle, the cartridge serving the purpose of the cannula of the predicate submission. The device action as a synthetic, inorganic, biocompatible and osteoconductive scaffold into which new bone will grow is unchanged.

7. Conclusion

The device modification of this submission is to include a new package format. The new cartridge-handle format provides improved access to remote graft sites, This device modification does not result in a change in technological characteristics of the NovaBone Putty device. NovaBone Putty continues to be safe and effective as a non-structural osteoconductive bone void filler for osseous defects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

OCT 14 2011

Novabone Products, LLC
% Mr. David M. Gaisser
13631 Progress Boulevard, Suite 600
Alachua, Florida 32615

Re: K112773
Trade/Device Name: NovaBone Putty – Bioactive Synthetic Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 22, 2011
Received: September 23, 2010

Dear Mr. Gaisser:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin M. Keith

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K112773

Device Name: NovaBone Putty – Bioactive Synthetic Bone Graft

Indications For Use:

NovaBone Putty – Bioactive Synthetic Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed 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.

NovaBone Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112773