K091484

NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

JUN 15 2009

Special 510(k): Device Modification Summary 05/15/09
NovaBone Dental Putty – Bioactive Synthetic Bone Graft

1. Submitter Information:

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Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Dental 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 Dental Putty – Bioactive Synthetic Graft [K063549]
Predicate #2:	PerioGlas – Bone Graft Particulate [K040278]
Predicate #2:	NovaBone Putty – Bioactive Synthetic Bone Graft [K082672]

4. Device Description

NovaBone Dental Putty is an osteoconductive, bioactive, bone void filler device. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects and is supplied sterile. 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. The mixed device is supplied sterile, packaged either in a PET-G tray or in a disposable plastic syringe. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles are slowly absorbed and replaced by new bone tissue during the healing process. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects. It is supplied sterile.

5. Intended Use

NovaBone Dental Putty is indicated to be packed into bony voids or gaps to fill and/or augment oral, dental intraosseous, and craniofacial defects. These defects

may include: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. NovaBone Dental Putty may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either as a bone graft extender.

6. Technological Characteristics

The technological characteristics of the NovaBone Dental Putty device are similar to those of the predicates. The device and the predicates are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The device indications are unchanged from those of the predicate devices. The device is intended to be used alone, or in combination with autogenous or allograft bone.

The NovaBone Dental Putty device of this submission is identical in composition and formulation to the NovaBone Dental Putty and NovaBone Putty predicate devices. The primary component of NovaBone Dental Putty also is identical to the bioactive glass (45S5 Bioglass) particulate found in the PerioGlas predicate. This synthetic material is both biocompatible and osteoconductive. The NovaBone Dental 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.

The syringe package format as described in this submission is a product line extension, increasing the device package format availability. Similar syringe packages have been cleared for the NovaBone Putty [K082672] and PerioGlas [K040278] predicates.

7. Warnings and Precautions

NovaBone Dental Putty does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth. In cases where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

NovaBone Dental Putty is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. NovaBone Dental Putty must not be used to gain screw purchase or to stabilize screw placement.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery. Complications specific to oral/dental use are those as may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation.

9. Conclusion

The NovaBone Dental Putty device modification subject to this submission is to include a filled-syringe package format to augment the current tray-in-pouch format. This device modification does not result in a change in technological characteristics of the 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
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2009

Mr. David M. Gaisser
Vice President, Operations/Regulatory Affairs/Quality Assurance
NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K091484
Trade/Device Name: NovaBone Dental Putty – Bioactive Synthetic Bone Graft
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: May 15, 2009
Received: May 19, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K091484

Device Name: NovaBone Dental Putty – Bioactive Synthetic Bone Graft

Indications For Use:

The intended use of NovaBone Dental Putty is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and craniofacial defects. It is used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone) or may be mixed with either (typically 1:1 ratio v/v) as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge Augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/ placement)
- Sinus lifts
- Cystic cavities
- Cranio-facial augmentation

For larger defects, a mixture of NovaBone Dental Putty with an equal volume of allograft or autograft bone and bone marrow may improve new bone formation.

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)

Lori Hurley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091484