K112428

NOVABONE
DRIVING INNOVATION IN OSTEOBIOLOGICS

DEC 16 2011

510(k) Summary 08/19/11
NovaBone Dental Morsels – Bioactive Synthetic Bone Graft

1. Submitter Information:

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

2. Name of Device:

Trade Name:	NovaBone Dental Morsels – Bioactive Synthetic Bone Graft
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 872.3930
Regulation Name:	Bone Grafting Material, Synthetic
Regulatory Class:	Class II
Product Code:	LYC

3. Legally Marketed Predicate Device:

Predicate #1:	PerioGlas – Bone Graft Particulate [K053387, K040278, K992416, K962494, K930115]
Predicate #2:	NovaBone Porous – Bone Graft Scaffold [K060432, K090731]

4. Device Description

NovaBone Dental Morsels is an osteoconductive, bioactive, bone void filler device. The device is intended for dental intraosseous, oral, and maxillofacial bony defects. It is a one-component, resorbable bone void filler composed of a synthetic calcium phospho-silicate (Bioglass) particulate, fused into a bulk porous form having a multidirectional interconnected porosity. The device is supplied sterile, packaged in a disposable PET-G tray with heat-sealed lid. On implantation, NovaBone Dental Morsels undergoes a time-dependent surface modification, resulting in the formation of a calcium phosphate layer on the device surfaces. The device acts as a scaffold, with new bone infiltrating the porous structure. NovaBone Dental Morsels is progressively resorbed and replaced by new bone tissue during the healing process.

5. Indications for Use

The intended use of NovaBone Dental Morsels is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and maxillofacial bone defects. It is used in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone). Typical uses include: periodontal / infrabony defects; ridge augmentation (sinusotomy,

osteotomy, cystectomy); extraction sites (ridge maintenance/augmentation, implant preparation/ placement); sinus lifts; cystic cavities; oral and maxillo-facial augmentation.

6. Technological Characteristics and Substantial Equivalence

The technological characteristics of the NovaBone Dental Morsels device are similar to the predicate devices. A side-by-side comparison of the devices is given in Table 3.1. The new device and the predicates are designed as osteoconductive space-filling devices that aid in the bone repair process. The device indications are unchanged from those of the PerioGlas predicate device. The device is intended to be used alone, or in combination with autogenous or allograft bone.

The technological characteristics of the NovaBone Dental Morsels are similar to those of the predicates in terms of the device material. All three devices are a single-phase, calcium phospho-silicate material. Physically, the Dental Morsels device has an open pore structure identical to the NovaBone Porous predicate. The Dental Morsels particle size is between that of the PerioGlas predicate and the larger orthopedic NovaBone Morsels device.

NovaBone Dental Morsels and the predicates are designed to be gently packed into defect sites, functioning as a non-structural scaffold for the body's natural healing and bone regeneration process. The Dental Morsels and the PerioGlas predicate are indicated for oral and dental indications while NovaBone Porous is intended for orthopedic bone defects. The device acts as a synthetic, inorganic, biocompatible and osteoconductive scaffold into which new bone will grow.

Information provided in this submission includes compositional analysis, *in vivo* bone void testing, and ISO 10993 biocompatibility results. Test results indicate that this material is biocompatible and safe for its intended use.

7. Conclusion

The NovaBone Dental Morsels device serves as a bone void filler for non-structural osseous defects for dental intraosseous, oral, and maxillofacial indications. The device physical structure is modified from the PerioGlas predicate to provide a device with interconnected porosity for tissue ingrowth. This device modification does not result in a change in technological characteristics of the device. *In vivo* study data were presented supporting the osteoconductive nature of the device demonstrating new bone formation at early post-implantation periods, with no evidence of local or systemic adverse effects related to the device observed. Additional supporting *in vitro* data were supplied.

Table 3.1 Comparison of the New Device to the Marketed Predicate Devices

Substantial Equivalence Comparison	**New Device** NovaBone Dental Morsels	**Predicate #1** PerioGlas [K040278, K992416, K962494, K930115]	**Predicate #2** NovaBone Porous [K060432, K090731]
Intended Use	A non-structural osteoconductive bone void filler for osseous defects.	Same as new device	Same as new device
Indications	To fill and/or augment oral, dental intraosseous, and maxillofacial bone defects Classif. Code: LYC	Same as new device Classif. Code: LYC	Orthopedic bony voids in gaps of the skeletal system (i.e., the extremities and pelvis) Classif. Code: MQV
Application	Gently packed into defect sites as a non-structural scaffold for the body's natural healing and bone regeneration processes.	Same as new device	Same as new device
Material	Inorganic calcium phospho-silicate, thermally formed and bound together in a sodium silicate network. Individual particles fused to form porous graft material	Same material as new device, but the individual particles are not fused together to create a porous material.	Same as new device
Device Porosity	Interconnected pore structure, with 40-60% pore volume and 50-400 micron pore size,	Dense individual particles. Space between packed particles provides approx 50% pore volume	Same as new device
Particle Sizes	500 – 1000 microns and 1000 – 2000 microns	90 – 710 microns Smaller than new device	2000 – 5000 microns Larger than new device
Device Action	Ion diffusion and exchange at particle surfaces form a calcium phosphate surface layer, which acts as a scaffold for new bone formation throughout the graft site via osteoconduction. Continued ion diffusion and exchange results in material resorption.	Same as new device	Same as new device
Performance	Bone infiltration occurs throughout the graft site via osteoconduction, resulting in increased graft site mechanical stiffness and strength	Same as new device	Same as new device.

Table 3.1 Comparison of the New Device to the Marketed Predicate Devices

Substantial Equivalence Comparison	**New Device** NovaBone Dental Morsels	**Predicate #1** PerioGlas [K040278, K992416, K962494, K930115]	**Predicate #2** NovaBone Porous [K060432, K090731]
Bone remodeling	New bone grows into the graft area via osteconduction. The material is slowly absorbed and replaced by the host bone.	Same as new device	Same as new device.
Resorption Rate	Majority absorbed by six months	Same as new device	Same as new device
Biocompatibility	Biocompatible, non-antigenic; full ISO 10993 testing	Same as new device	Same as new device
Mechanical	Particulate material; not intended for use in load-bearing defects without proper internal or external fixation	Same as new device	Same as new device
Package Format	PETG cups with Tyvek® lids	PETG cup / Tyvek lid and PP syringe in foil pouch	PETG cup / Tyvek lid and PP syringe in foil pouch
Sterility	Gamma Irradiation SAL 10^{-6}	EO Gas (cups/lids); and Gamma (syringe) both SAL 10^{-6}	EO Gas (cups/lids) and Gamma (syringe) both SAL 10^{-6}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David M. Gaisser
Vice President – Operations/RA/QA
NovaBone Products, LLC
13631 Progress Boulevard, Suite 600
Alachua, Florida 32615

DEC 16 2011

Re: K112428
Trade/Device Name: NovaBone Dental Morsels – Bioactive Synthetic Bone Graft
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: November 29, 2011
Received: December 15, 2011

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): _____

Device Name: NovaBone Dental Morsels – Bioactive Synthetic Bone Graft

Indications For Use:

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- Periodontal / infrabony defects
- Ridge augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/ placement)
- Sinus lifts
- Cystic cavities
- Oral and maxillofacial augmentation

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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