APR 4 2006

NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

K060432

510(k) Summary
NovaBone Porous - Bone Graft Scaffold

02/17/06

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13709 Progress Boulevard, #33 Alachua, FL 32615
Telephone:	(386) 462-7660
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Porous – Bone Graft Scaffold
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Classification Name:	Unknown

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone – Resorbable Bone Graft Substitute [K021336]
Predicate #2:	ProOsteon 500R – Resorbable Bone Graft [K990131]

4. Device Description

NovaBone Porous is an osteoconductive bioactive device. 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. On implantation, NovaBone Porous 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 Porous is progressively resorbed and replaced by new bone tissue during the healing process.

5. Intended Use

NovaBone Porous is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Porous 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 an osteoconductive scaffold that resorbs and is replaced with bone during the healing process.

6. Technological Characteristics

The technological characteristics of the NovaBone Porous device are similar to those of the predicates, although not identical. Chemically, the device is comprised of the same material as the NovaBone predicate. Some changes in material crystalline structure have been made during the porous device formation process, but the osteoconductive nature of the device in unchanged. Physically, the device is designed as a bulk, porous osteoconductive space-filling device, similar to the Pro Osteon 500R predicate. It is designed 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 acts as a synthetic, inorganic, biocompatible and osteoconductive scaffold into which new bone will grow.

The NovaBone Porous device is a single-phase bioactive glass (45S5 Bioglass) device. The device indications are the same as those for the predicate devices.

7. Warnings and Precautions

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

NovaBone Porous is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. NovaBone Porous 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.

9. Conclusion

NovaBone Porous functions as a bone void filler for non-structural osseous defects. *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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Nova Bone Products, LLC
C/o Mr. David M. Gaisser
VP, Operations/RA/QA
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K060432
Trade/Device Name: NovaBone Porous – Bone Graft Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 17, 2006
Received: February 22, 2006

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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): _____

Device Name: NovaBone Porous - Bone Graft Scaffold

Indications For Use:

NovaBone Porous - Bone Graft Scaffold is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Porous 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.

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 General, Restorative, and Neurological Devices

510(k) Number K040432