NOV - 3 2005

K052494

510(k) Summary 09/09/05
NovaBone - Resorbable Bone Graft Substitute

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 – Resorbable Bone Graft Substitute
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]

4. Device Description

NovaBone is a one-component resorbable bone void filler composed of a synthetic calcium phospho-silicate (Bioglass) particulate designed specifically for its absorbability and osteoconductive nature. NovaBone is progressively resorbed and replaced by new bone tissue during the healing process.

5. Intended Use

NovaBone is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, 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.

6. Technological Characteristics

The technological characteristics of NovaBone device have not changed. The device is designed as an osteoconductive space-filling particulate 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 acts as a particulate, synthetic, inorganic, biocompatible and osteoconductive material.

The NovaBone device is a single-phase bioactive glass (45S5 Bioglass) particulate device. No changes to the device or its indications have been made with this submission. The purpose of this premarket notification is to expand the product claims to cover the claim of the device being osteostimulative. After implantation, surface reactions result in the absorption of the device material and concurrent new bone tissue formation. These surface reactions result in an osteostimulative affect, defined as the stimulation of osteoblast proliferation and differentiation during *in vitro* osteoblast cell culture studies as evidenced by increased DNA content and elevated osteocalcin and alkaline phosphatase levels.

7. Warnings and Precautions

NovaBone 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 is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. NovaBone 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 functions as a bone void filler for non-structural osseous defects. *In vivo* study data were presented supporting a superior rate of osteconduction and bone formation at early post-implantation periods compared to hydroxyapatite devices. *In vitro* cell culture data were presented to demonstrate and define the osteostimulative nature of the NovaBone device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2005

David M. Gaisser
VP, Operations/RA/QA
NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K052494
Trade/Device Name: NovaBone – Resorbable Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 9, 2005
Received: September 21, 2005

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
Acting 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): K052494

Device Name: NovaBone - Resorbable Bone Graft Substitute

Indications For Use:

NovaBone Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, 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.

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 K052494