

JUL 25 2002

KO2 1336

510(k) Summary 4/24/02
NovaBone® - Resorbable Bone Graft Substitute



1. Submitter Information:

Name: NovaBone Products, LLC
Address: One 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: Pro Osteon 500R [K980817]
Predicate #2: Wright Plaster of Paris Pellets [K963562]

4. Device Description

NovaBone® is a synthetic resorbable osteoconductive bone graft substitute particulate entirely composed of a calcium phospho-silicate material. The inorganic calcium and phosphorous components are thermally incorporated in a sodium silicate network designed specifically for its resorbability and osteoconductive nature. NovaBone is progressively resorbed and replaced by host bone during the healing process

5. Intended 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.

6. Technological Characteristics

The technological characteristics of NovaBone, ProOsteon 500R, and Wright Plaster of Paris Pellets are similar, although not identical. NovaBone, ProOsteon 500R, and Wright Plaster of Paris Pellets are designed to be osteoconductive space-filling particulates to be gently packed into defect sites and to be used as a non-structural scaffold for the body's natural healing and bone regeneration process. To meet this design, NovaBone, ProOsteon 500R, and Wright Plaster of Paris Pellets are similar in nature; all three devices are particulate, synthetic, inorganic, biocompatible and osteoconductive materials.

The main technological characteristic difference between NovaBone, ProOsteon 500R, and Wright Plaster of Paris Pellets is their composition, each being composed of a different synthetic material. NovaBone is composed of Bioglass® (see description), ProOsteon 500R is composed of calcium carbonate with a thin calcium phosphate coating, and Wright Plaster of Paris Pellets is composed of calcium sulfate with stearic acid as a tableting aid. These different materials have different absorption rates. The Wright Plaster of Paris Pellets are absorbed between four and eight weeks, depending on the graft site, size and material used. NovaBone and ProOsteon 500R have a similar, slower absorption rate, but both are still substantially absorbed within the six-month timeframe normally associated with bone remodeling. For all three devices, bone forms throughout the graft site with the material being absorbed and replaced by new bone tissue.

The performance of NovaBone has been compared to ProOsteon 500R and to Wright Plaster of Paris Pellets in side-by-side comparison studies. Three such studies were conducted:

- A. A 6mm diameter defect in the distal femur of rabbits to compare NovaBone and ProOsteon 500R in the same animal. At three months, both materials showed similar residual graft material area, with a substantial reduction in NovaBone graft particulate area from initial post-implantation values. The graft site biomechanical properties were not statistically different between graft materials while new bone formation was greater for NovaBone than for the ProOsteon 500R.
- B. Comparisons between NovaBone and Wright Plaster of Paris Pellets were conducted in a goat femoral model. A 10mm diameter defect was created in the distal femur and evaluated at six weeks and six months. The Wright Plaster of Paris Pellets was mostly absorbed by six weeks, while some residual NovaBone was observed out to six months. The graft site biomechanical properties were similar between graft materials, with new bone formation greater for NovaBone than for the Wright Plaster of Paris Pellets.

C. Comparisons between NovaBone and Wright Plaster of Paris Pellets were also conducted in an iliac crest model in sheep. Unicortical defects were made and a channel was reamed in the cancellous space of the superior iliac crest. Both NovaBone and Wright Plaster of Paris Pellets showed better bone regeneration than empty control sites at six weeks and six months. Histologically, the NovaBone defects had greater amounts of new bone formation at six weeks.

7. Warnings and Precautions

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

NovaBone is intended for use by surgeons 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 is claimed to be substantially equivalent to ProOsteon 500R and Wright Plaster of Paris Pellets as a non-structural osteoconductive bone void filler for osseous defects. Side-by-side comparative *in vivo* performance data was presented, with no evidence of local or systemic adverse effects related to the device observed. Additional supporting *in vitro* and clinical data were supplied.

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

Substantial Equivalence Comparison	<u>This Device</u> NovaBone	<u>Predicate #1</u> Pro Osteon 500R K980817	<u>Predicate #2</u> Wright Plaster of Paris Pellets K963562
Intended Use	A non-structural osteoconductive bone void filler for osseous defects.	Same as new device	Same as new device
Indications	Bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis)	Same as new device	Same as new device
Application	To be 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.	Inorganic calcium carbonate core with a thin, hydrothermally-formed inorganic calcium phosphate layer	Inorganic calcium sulfate, pressed and bound into pellets using a stearic acid tableting aid.
Device Action	Ion diffusion and ion exchange occur between the NovaBone particle surfaces and the in vivo environment to form a calcium phosphate surface layer. The surface layer acts as a scaffold for new bone formation throughout the graft site via osteoconduction. Continued ion diffusion and exchange results in material resorption.	The pre-existing calcium phosphate layer acts as a scaffold for new bone formation and ingrowth via osteoconduction. The calcium phosphate layer is slowly resorbed to expose the faster resorbing calcium carbonate core.	The pellets react with bodily fluids to dissolve to form calcium phosphate mineral deposits that act as a scaffold for ingrowing bone, the dissolved calcium being incorporated by new bone tissue.
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.
Bone remodeling	New bone grows into the graft area via osteoconduction. 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	Majority absorbed by six to eight weeks

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

Substantial Equivalence Comparison	<u>This Device</u> NovaBone	<u>Predicate #1</u> Pro Osteon 500R K980817	<u>Predicate #2</u> Wright Plaster of Paris Pellets K963562
Biocompatibility	Biocompatible, non-antigenic	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
Sterility	ETO	Gamma	Gamma
Voluntary Standards met	Trace Element levels as cited in ASTM F 1538 -94, "Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation"	None known	None known



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2002

Mr. David M. Gaisser
Director of Operations
NovaBone Products, LLC
1 Progress Boulevard, #33
Alachua, FL 32615

Re: K021336
NovaBone®- Resorbable Bone Graft Substitute
Regulatory Class: unclassified
Product Code: MQV
Dated: April 24, 2002
Received: April 26, 2002

Dear Mr. Gaisser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

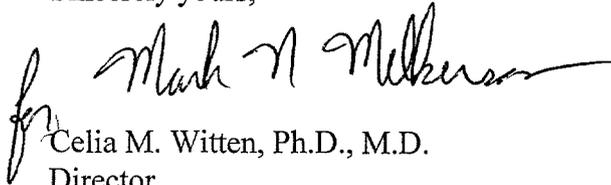
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. David M. Gaisser

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at ~~(301) 594-4639~~. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name.

Celia M. Witten, Ph.D., M.D.

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): K021336

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021336

Prescription Use

OR
(Per 21 CFR 801.109)

Over-The-Counter Use