nanotherapeutics

K062459

FEB 26 2007

510(k) Summary

Origen™ DBM with Bioactive Glass

Date: February 16, 2007

Submitted by: Nanotherapeutics, Inc.
12085 Research Drive
Alachua, FL 32615

Representative: Dennis Tomisaka, M.S., MBA
VP Operations and Product Development
Phone: (386) 462-9663
FAX: (386) 462-2087

Proprietary Name: Origen™ DBM with Bioactive Glass

Common Name: Bone Void Filler, Bone Graft Substitute

Classification Name: Filler, Calcium Sulfate Preformed Pellets, Section 88.3045.

Classification Code: MBP, MQV, Class II

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
Novabone	NovaBone Products, Inc.	K021336
Osteofil Paste DBM with Inert Carrier Porcine Collagen	Regeneration Technologies, Inc.	K043420

Description: Origen™ DBM with Bioactive Glass is a malleable, putty-like bone-void filler. The product is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles, both coated with gelatin derived from porcine skin. These coated particles are packaged dry in a single use, polypropylene syringe (20 cc or 5 cc), double-wrapped in peel-back pouches, and final packaged in a dust cover paperboard carton. The 20 cc syringe will be filled with either of two different fill quantities of dry powder, identified as 10 cc or 5 cc final product volume. The 5 cc syringe will be filled with two additional fill quantities of dry powder, identified as 2.5 cc or 1 cc final product volume. Origen™ DBM with Bioactive Glass is intended for single patient use only.

At point of use, the surgeon will reconstitute the product with an appropriate sterile solution of his/her choice (WFI, sterile normal saline). The coated particles rehydrate in less than 30 seconds and do not require mixing to form a uniform paste or putty. The material is then gently extruded by the surgeon into the appropriate bone voids. Origen™ DBM with Bioactive Glass is progressively resorbed and replaced by host bone during the osteo-remodeling process.

Indications for Use:	Origen™ DBM with Bioactive Glass is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be gently placed into bony voids or gaps of the skeletal structure (e.g., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. The product provides a bone graft substitute that remodels into the recipient's skeletal system.
Technological Characteristics:	Origen™ DBM with Bioactive Glass is substantially equivalent to the two identified predicate devices, Novabone (K021336) and Osteofil Paste (DBM) with Inert Carrier Porcine Collagen (K043420), with respect to materials and intended use in that it consists of human demineralized bone matrix (DBM) and non-tissue additives. It is provided dry and is reconstituted at the point of use into a paste-like, malleable form that can be molded or manipulated into bony defects. Origen™ DBM with Bioactive Glass is composed of approximately equal parts, by mass, of DMB, BioActive Glass, and porcine gel. Novabone (K021336) and Osteofil Paste (DBM) with Inert Carrier Porcine Collagen (K043420) were chosen as Predicate devices due to their Substantial Equivalence to Origen™ DBM with Bioactive Glass in their declared Indications for Use, Design, and Materials. NovaBone is a one-component resorbable bone void filler compound of synthetic calcium phosphor-silicate (45S5 Bioglass) particulate. This material is chemically and physically analogous to the glass material used in the Origen™ device. The Intended Use of both Origen™ and NovaBone is for bony void or gaps that are not intrinsic to the stability of the bony structure. Osteofil Paste DMB is comprised of Demineralized Bone Matrix (DBM) in a porcine collagen carrier. Both the RTI and the Nanotherapeutics DBM are sourced from donated human tissue and both bone void products are coated with gelatin derived from porcine skin. Each lot the demineralized bone matrix in Origen™ DBM with Bioactive Glass is screened for osteoinductivity in an *in vitro* assay, which has been correlated to the athymic rat model.
Non-Clinical Performance Tests:	Nanotherapeutics has conducted a GLP compliant study comparing bone formation and subsequent healing with Origen compared to autogenous bone graft and Predicate Devices: Novabone (K021336); and, Osteofil Paste DBM with Inert Carrier Porcine Collagen (K043420).
Conclusion:	The results of this study indicate that Origen™ DBM with Bioactive Glass is substantially equivalent to the predicate devices.
Safety Information:	Human demineralized bone used in Origen™ DBM with Bioactive Glass is single-donor processed and biocompatible.

A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA, envelope, and non-envelope virus. The test viruses included: 1. bovine diarrhea virus (BVDV); hepatitis A virus (HAV); human immunodeficiency virus type 1 (HIV-1), porcine parvovirus (PPV); and pseudorabies virus (PrV). This study demonstrates the demineralization process used on donor bone contained in Nanotherapeutics' Origen™ DBM with Bioactive Glass effectively eliminates or reduces the virus responsible for potential infectious disease, which include HIV and Hepatitis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nanotherapeutics, Inc.
c/o Ms. Paula Wilkerson RAC, CRA
Actualized Science, LLC
12337 NW 9th Lane
Newberry, FL 32615

FEB 26 2007

Re: K062459
Trade Name: Origen™ DBM with Bioactive Glass
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: December 4, 2006
Received: December 5, 2006

Dear Ms. Wilkerson:

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

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

nanotherapeutics

SECTION 4 INDICATIONS FOR USE

510(k) Number (if known): K062459

Device Name: Origen™ DBM with Bioactive Glass

Indications For Use:

Origen™ DBM with Bioactive Glass is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be placed into bony voids or gaps of the skeletal system (e.g., 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 graft substitute that remodels into the recipient's skeletal system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062459