FEB - 3 2005

K050025

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Angstrom Medica, Inc. 150-A New Boston Street, Woburn, MA 01801
Official Contact:	Paul J. Mraz, CEO Telephone: (781) 933-6121 FAX: (781) 933-5981
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone: (858) 792-1235 FAX: (858) 792-1236 e-mail: flarson@paxmed.com

DEVICE NAME

Classification Name:	Filler, calcium sulfate preformed pellets
Trade/Proprietary Name:	NanOss™ Bone Void Filler
Common Name:	bone void filler
Product Code:	MQV

DEVICE CLASSIFICATION

Calcium sulfate preformed pellets have been classified by FDA as Class II, Special Controls, in a Final Rule effective July 2, 2003 (68 FR 32635) (21 CFR 888.3045). Calcium phosphate devices have been cleared as substantially equivalent to calcium sulfate devices.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514.

INTENDED USE

NanOss Bone Void Filler is intended only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product 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 by the growth of new bone during the healing process.

DEVICE DESCRIPTION

NanOss Bone Void Filler is an osteoconductive, resorbable, calcium phosphate implant for use as a bone graft substitute or bone void filler. The device consists of prefabricated cylindrical calcium phosphate pellets. The device is radiopaque and is presterilized for single use. The nanocrystalline processing of the material results in sintered hydroxyapatite pellets that are translucent and uniform in density and strength.

EQUIVALENCE TO MARKETED PRODUCT

NanOss Bone Void Filler is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices. The intended use, design and functional characteristics of NanOss Bone Void Filler and the predicate devices are substantially the same. These devices include Biomet Calcium Phosphate Granular Bone Void Filler (K011531); NovaBone Resorbable Bone Graft Substitute (K021336); Wright Medical Technology Osteoset Resorbable Mini Bead Kit (K010532); Orthovita Vitoss Scaffold (K994337) and Interpore Pro Osteon 500R (K990131). These devices all are intended to fill voids or gaps in osseous defects, are not intended to be load-bearing and consist of a variety of calcium compounds.

NanOss Bone Void Filler pellets are chemically similar to the calcium phosphate predicates, with the expected phase purity and calcium/phosphorus stoichiometry, and with trace element levels below the limit set by ASTM F1185. Density is essentially the theoretical density for ceramic hydroxyapatite and bulk density is in the expected range for small cylindrical pellets. Dissolution behavior is within the range of that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Mr. Floyd G. Larson
Angstrom Medica, Inc.
C/o Paxmed International
4329 Graydon Road
San Diego, California 92130

Re: K050025
Trade/Device Name: NanOss™Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 04, 2005
Received: January 07, 2005

Dear Mr. Larson:

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.

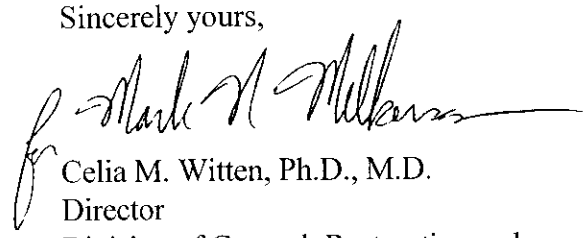
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.html

Sincerely yours,



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

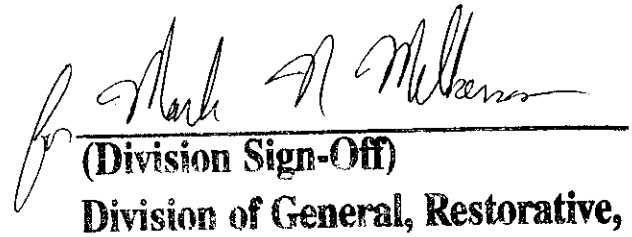
Indications for Use

510(k) Number (if known): _____

Device Name: NanOss™ Bone Void Filler

Indications for Use:

NanOss Bone Void Filler is intended only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product 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 by the growth of new bone during the healing process.



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

510(k) Number K050025

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