K070751

REVISED FROM MARCH 5, 2007

OCT 15 2007

5. 510(K) SUMMARY

510(k) Summary for IsoTis OrthoBiologics, Inc. OrthoBlast II Putty and Paste

5.1 SPONSOR

IsoTis OrthoBiologics, Inc.
2 Goodyear, Suite B
Irvine, CA 92618
U.S.A

Contact Person:	Karon Morell
Telephone:	(949) – 855-7168
Main Tele:	(949) – 595-8710
Facsimile:	(949) – 595-8711
Date Prepared:	December 14, 2006

5.2. DEVICE NAME

Proprietary Name:	OrthoBlast® II Demineralized Bone Matrix Putty and Paste
Regulation Name:	Human Bone Graft Material
Regulatory Class:	II
Product Code: MQV	

5.3. PREDICATE DEVICE

DynaGraft II (Demineralized Bone Matrix):	K040419
OrthoBlast II Paste and Putty	K050642

5.4. DEVICE DESCRIPTION

OrthoBlast® II DBM Putty and Paste is derived from selected donated human bone tissue that has been processed into particles. The bone particles are subsequently demineralized using a hydrochloric acid process. The demineralized bone matrix (DBM) is combined with a reverse phase carrier, cancellous chips from the same donor, and then formulated to a paste or putty-like consistency.

OrthoBlast® II DBM Putty and Paste are osteoconductive and osteoinductive bone filling material. The osteoinductive potential is demonstrated in athymic mouse model.

5.5 INTENDED USE (EXPANDED INDICATION FOR SPINE APPLICATIONS)

For orthopedic use, OrthoBlast II Paste and Putty are intended for use as an autograft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps that are not intrinsic to the stability of the bony structure. The OrthoBlast II products are indicated to be packed gently into bony defects of the skeletal system. These defects may be surgically created or from the result of traumatic injury to the bone.

5.6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

OrthoBlast® II DBM Putty and Paste has obtained previous 510(k) clearance for orthopeadic (K050642) indications.

OrthoBlast II is substantially equivalent to DynaGraft II Putty previously cleared by FDA (K040419). OrthoBlast II is similar to DynGraft II as both products utilize ground, human donor, demineralized cortical bone to manufacture the product. Both products utilize an inactive poloxamer reverse phase carrier (RPM) as a containing agent to provide the product's putty-like consistency and handling characteristics. The proposed and predicate devices have the identical indications for use, are provided sterile, and are intended for single patient use.

The main difference between the two products is that DynaGraft II Putty and Gel contains more demineralized bone by weight and volume and less synthetic carrier than OrthoBlast II pastes and putties. OrthoBlast II also incorporates the cancellous bone tissue in particulate form from the same donor while DynaGraft II does not.

5.7 PERFORMANCE DATA

Product safety and effectiveness is adequately supported by the substantial equivalence information, materials data, and animal test results provided in this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2007

Isotis Orthobiologics, Inc.
% Ms. Karon Morell
Vice President Quality Assurance and Regulatory Affairs
2 Goodyear, Suite B
Irvine, CA 9261

Re: K070751
Trade/Device Name: Orthoblast II DBM Demineralized bone matrix paste and putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: June 14, 2007
Received: June 18, 2007

Dear Ms. Morell:

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.

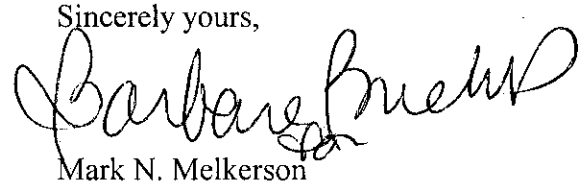
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

4) INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K070751

Device Name: OrthoBlast® II DBM Demineralized Bone Matrix Paste and Putty

Indications for Use:

Indications for Use

For orthopedic use, the OrthoBlast II Paste and Putty are intended for use as an autograft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps that are not intrinsic to the stability of the bony structure. The OrthoBlast II products are indicated to be packed gently into bony defects of the skeletal system. These defects may be surgically created or from the result of traumatic injury to the bone

Prescription Use ___X___ 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)

Barbara Ruehl for mcm

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

510(k) Number K070751