K060332

# 5.0 510(K) SUMMARY

MAR 29 2006

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

## 1. SPONSOR

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

Contact Person: Eliane Schutte
Telephone: +31-(0) 30-2295253
Facsimile: +31-(0) 30-2280255
Date Prepared: February 03, 2006

## 2. DEVICE NAME

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

## 3. PREDICATE DEVICE

DynaGraft II Dental (Demineralized Bone Matrix) [K043573]

## 4. DEVICE DESCRIPTION

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

## 5. INTENDED USE (EXPANDED INDICATION FOR DENTAL APPLICATIONS)

OrthoBlast® II DBM Paste and Putty are bone filling materials indicated for augmentation or reconstructive treatment of alveolar ridge. This includes:

- Filling of defects after root resection, apicoectomy and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge

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- Elevation of maxillary sinus floor

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

OrthoBlast® II DBM Paste and Putty is substantially equivalent to DynaGraft II Dental Putty previously cleared by FDA under 510(k) K043573. Both products utilize ground, human donor cortical demineralized bone for 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 device and predicate device have the same 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 same donor's cancellous tissue in particulate form while DynaGraft II does not.

## 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

MAR 2 9 2006

Isotis NV
Ms. Elaine Schutte
Director of Regulatory Affairs
Isotis Orthobiologics, Incorporated
2 Goodyear, Suite B
Irvine, California 92618

Re: K060332
Trade/Device Name: OrthoBlast® II DBM Demineralized Bone Matrix Paste and Putty
Regulation Number: 872.3930
Regulation Name: Bone Graft Material
Regulatory Class: II
Product Code: NUN
Dated: February 8, 2006
Received: February 9, 2006

Dear Ms. Schutte:

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 (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.

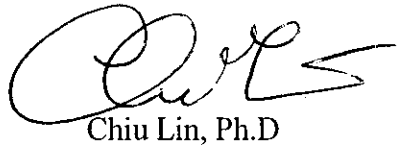
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

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# 4.0 INDICATIONS FOR USE STATEMENT

## Indications for Use

**510(k) Number (if Known):**

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

**Indications for Use:**

OrthoBlast® II DBM Paste and Putty are bone filling materials indicated for augmentation or reconstructive treatment of alveolar ridge. This includes:

- Filling of defects after root resection, apicoectomy and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor

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)

[illegible]logy, General Hosp[illegible]
[illegible]al Dental Devices

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