DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2005

Isotis Orthobiologics, Incorporated
c/o Mr. Paul Doner
2 Goodyear, Suite B
Irvine, California 92618

Re: K043573
Trade/Device Name: DynaGraft II Dental
Regulation Number: 21 CFR 872.3930
Regulation Name: Human Bone Graft Material
Regulatory Class: II
Product Code: NUN
Dated: July 25,2005
Received: July 26,2005

Dear Mr Doner:

This letter corrects our substantially equivalent letter of July 29,2005, regarding the product code.

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.

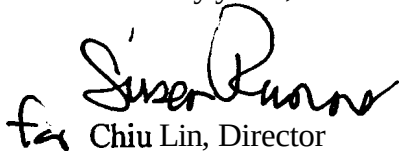
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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), please contact the Office of Compliance at (240) 276-0115. 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,



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

Enclosure

K043573

JUL 29 2005

# 510(k) Summary for IsoTis OrthoBiologic DynaGraft® II Dental

## 1. SPONSOR

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

Paul Doner
Director of Quality Assurance and Regulatory Affairs
Telephone: 949-855-7168
Fax: 949-595-8711

E. Schutte
Telephone: +31-(0) 30-2295125
Facsimile: +31-(0) 30-2280255
Date Prepared: December, 2004

## 2. DEVICE NAME

Proprietary Name: DynaGraft® II Dental
Common/Usual Name: Human Bone Graft Material
Classification Name: Bone void filler (Unclassified)

## 3. PREDICATE DEVICES

Tissue Bone Matrix Sponge (K960267), autograft.

## 4. DEVICE DESCRIPTION

DynaGraft® II Dental 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 and formulated to a gel or putty-like consistency.

## 5. INTENDED USE

DynaGraft II Dental is a bone filling material 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
- Treatment of periodontal defects

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

DynaGraft® II Dental and TBM sponge (K960267) are similar in design, construction and function. The main human component of donor DBM is the same. The

K043573

DynaGraft II products contain the same organic elements as natural bone (autologous bone graft). The proposed and predicate devices are osteoconductive and have been evaluated for osteoinductive potential. The DynaGraft II product, the TBM sponge and the autologous bone graft provide an interconnected, porous scaffold and an environment for new bone ingrowth and stimulate bone growth. All products are provided sterile and for single patient use. The only difference between the proposed device and autograft is that proposed device is that it is donor bone which doesn't contain the mineral components, but a gel like reverse phase carrier. The main difference between TBM sponge and DynaGraft II is the different carrier. For TBM, collagen is used, for DynaGraft II a reverse phase carrier. These differences do not affect safety or effectiveness since they are all resorbable and carry out the same function. The safety and biocompatibility testing performed for DynaGraft® II and the long history of safe clinical use for allograft and poloxamer based products support the safe use of DynaGraft II. The donor bone in the DynaGraft II product meets the requirements of the AATB. The polymer meets the essential requirements of the USP.

## 7. TESTING

Pre-clinical animal data and clinical data demonstrate that DynaGraft® II support bone ingrowth and stimulates active bone formation in a variety of bony defects. Biocompatibility, extensive bench and animal testing as well as the clinical case studies using DynaGraft II have successfully been performed to confirm that the device is resorbed over time and allows bone repair.

Demineralized bone has been used in clinical practice for more than 25 years with no remarkable safety issues. The product to which DynaGraft II claims substantial equivalence; autograft, has been used safely for many years in the clinical environment.

# Indications for Use

**510(k) Number (if known): K043573**

**Device Name:** DynaGraft II Dental

**Indications for Use:**

DynaGraft II Dental is a bone filling material 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
- Treatment of periodontal defects

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043573