OCT 2 0 2004

K042706

510(k) Summary
for
IsoTis NV OsSatura™ Dental

1. SPONSOR

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

IsoTis NV
Prof. Bronkhorstlaan 10
3723 MB Bilthoven
The Netherlands

Contact Person: E. Schutte
Telephone: +31-(0) 30-2295125
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Date Prepared: September 10, 2004

2. DEVICE NAME

Proprietary Name: OsSatura™ Dental

Common/Usual Name: Synthetic bone graft material

Classification Name: Bone filling augmentation (Unclassified)

3. PREDICATE DEVICES

Interpore 200 porous hydroxyapatite® (K 860983)

BioOss Collagen (K974399)

4. DEVICE DESCRIPTION

OsSatura™ Dental is a synthetic, osteoconductive bone void filler, which consists of a biphasic ceramic (e.g. hydroxyapatite/tri-calcium phosphate) scaffold. The open

porous structure of OsSatura™ Dental is similar in structure to human cancellous bone. OsSatura™ Dental is available as irregular shaped chips of size 200μm - 2000μm.

5. INTENDED USE

OsSatura™ Dental is a bone filling augmentation material for used 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 and treatment of periodontal defects.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The OsSatura Dental and the predicate devices are all similar in design, materials of construction and function. The OsSatura™ Dental product and the predicate devices are all made of calcium salts. The proposed and predicate devices are osteoconductive. The OsSatura™ Dental product and all the predicate devices provide an interconnected, porous scaffold and an environment for new bone ingrowth. All of the devices are provided sterile and non-pyrogenic for single patient use. The only difference between the proposed device and the predicate devices is that they are composed of different forms of calcium phosphate salts. These minor differences do not affect safety or effectiveness since they all carry out the same function. The safety and biocompatibility testing performed for calcium phosphates and the long history of safe clinical use for hydroxyapatite and tri-calcium phosphate products support the safe use of OsSatura™ Dental. The hydroxyapatite and tri-calcium phosphate in the OsSatura™ Dental meet the requirements in ASTM F1185-88 and F1088-87. Additionally, testing performed on the proposed device confirmed that OsSatura™ Dental meets the applicable requirements of the FDA guidance documents on bone void fillers.

7. TESTING

Pre-clinical animal data demonstrate that OsSatura™ Dental chips support bone ingrowth into a variety of bony defects. Biocompatibility, extensive bench and animal testing using OsSatura Dental have successfully been performed to confirm that the device is degraded and resorbed over time and allow bone ingrowth.

Calcium-based ceramic materials, including hydroxyapatite and tri-calcium phosphate, have been used in clinical practice for more than 25 years with no

remarkable safety issues. The devices to which OsSatura™ Dental claims substantial equivalence Interpore 200 porous hydroxyapatite and Bio-Oss Collagen have been used safely for many years in the clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

Mr. Paul Doner
Regulatory Affairs Manager
IsoTis OrthoBiologics, Incorporated
2 Goodyear, Suite B
Irvine, California 92618
U.S.A

Re: K042706
Trade/Device Name: OsSatura™ Dental
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: September 23, 2004
Received: September 30, 2004

Dear Mr. Doner:

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.

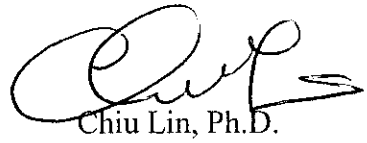
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

ISOTIS
OrthoBiologics™

510(k) Number (if known):

Device Name: OsSatura™ Dental

Indications for Use:

OsSatura™ Dental is a bone filling material indicated for augmentation or reconstructive treatment of the 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042706