K053371

OSSACUR

FEB 1 1 2006

510(K) Summary

A. Submitter Information

Submitter's Name:	OSSACUR® AG
Address:	Benzstrasse 2
	D-71720
	Oberstenfeld, Germany
Phone Number:	(+49) 7062 9404-0
Fax Number:	(+49) 7062 9404-20
Contact Person:	Arne Briest
Date of Preparation:	November 30, 2005

B. Device Name

Trade Name:	*OSSAPLAST™ DENTAL*
Common/Usual Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material
	§872.3930 (Product Code: LPK)

C. Predicate Devices

Trade Name:	calc-i-oss® (K042583)
Trade Name:	Cerasorb® DENTAL (K051443)

D. Device Description

OSSAPLAST DENTAL is a synthetic, implantable, resorbable, radiopaque β-tricalcium phosphate (β-TCP) ceramic in granulate form. It consists of pure-phase β-TCP [$Ca_3(PO_4)_2$] and is osteoconductive, with high interconnecting porosity.

OSSAPLAST DENTAL is supplied sterile in sealed glass vials, in various quantities. Each vial is packaged inside a Tyvek pouch to assure a double sterile configuration.

E. Intended Use

OSSAPLAST DENTAL is intended for use in filling, augmenting, or reconstructing periodontal or bony defects of the oro-maxillofacial region. It is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for GBR.

F. Technological Characteristics Summary

OSSAPLAST DENTAL does not incorporate any new technological characteristics as compared to the predicate devices. *OSSAPLAST DENTAL* and the predicate devices are made from the same material (pure-phase β-TCP) and conform to the standard specifications of ASTM F1088-04 for a medical grade β-TCP to be used in surgical implant applications. *OSSAPLAST DENTAL* is substantially equivalent to the predicate devices in regard to structure, porosity, form, packaging, sterility, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2007

Ossacur AG
C/O Ms. Kristi Kistner
Pacific Otter Works, Incorporated
975 Veronics Springs Road
Santa Barbara, California 93105

Re: K053374
Trade/Device Name: OSSAPLAST DENTAL™ Bone Grafting Material
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: November 30, 2005
Received: December 5, 2005

Dear Ms. Kistner:

This letter corrects our substantially equivalent letter of February 21, 2006.

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.

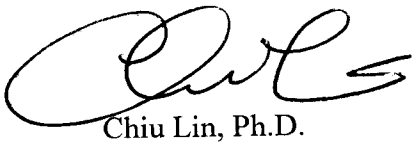
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 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

SECTION I-E.

Statement of Indications for Use

510(k) Number (if known): K053374

Device Name: OSSAPLAST™ DENTAL Bone Grafting Material

Indications for Use:

OSSAPLAST DENTAL is intended for use in filling, augmenting, or reconstructing periodontal or bony defects of the oro-maxillofacial region. It is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
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- Filling of peri-implant defects in conjunction with products intended for GBR.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ology, General Hospital,
... Dental Devices

K053374