K050416

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OSSACUR

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:	February 16, 2005

B. Device Name

Trade Name:	*OSSAPLAST™ ORTHO (1000 – 2000 µm)*
Common/Usual Name:	Bone Void Filler
Classification Name:	Resorbable calcium salt bone void filler device, §888.3045 (Product Code: MQV)

C. Predicate Devices

Trade Name:	Cerasorb® ORTHO (K014156)
Trade Name:	Cerasorb® M ORTHO (K040216)
Trade Name:	OSSAPLAST™ ORTHO (K042305)

D. Device Description

OSSAPLAST ORTHO (1000 – 2000 µm) 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.

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OSSAPLAST ORTHO (1000 – 2000 µm) 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 ORTHO is intended for use in filling bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone or a degenerative process. *OSSAPLAST ORTHO* is gradually resorbed and replaced with bone during the healing process. *OSSAPLAST ORTHO* is substantially equivalent in intended use to the predicate devices.

F. Technological Characteristics Summary

OSSAPLAST ORTHO (1000 – 2000 µm) does not incorporate any new technological characteristics as compared to the predicate devices. *OSSAPLAST ORTHO (1000 – 2000 µm)* 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 ORTHO (1000 - 2000 µm)* is substantially equivalent to the predicate devices in regard to structure, porosity, form, packaging, sterility, and biocompatibility.

G. Performance Data

Performance testing was conducted in conformance with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA (FDA/ODE, 6/2/2003)*. All data demonstrated that *OSSAPLAST ORTHO (1000 – 2000 µm)* is suitable for use as a bone void filler. It has been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2005

Ms. Kristi M. Kistner, RAC
President
OSSACUR AG
C/o Pacific Otter Works, Inc.
975 Veronica Springs Road
Santa Barbara, California 93105

Re: K050416
Trade/Device Name: OSSAPLAST™ ORTHO (1000 TO 2000 microns) Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 16, 2005
Received: February 18, 2005

Dear Ms. Kistner:

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological 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): K050416

Device Name: OSSAPLAST™ ORTHO (1000 to 2000 µm) Bone Void Filler

Indications for Use:
OSSAPLAST ORTHO is intended for use in filling bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone or a degenerative process. OSSAPLAST ORTHO is gradually resorbed and replaced with bone during the healing process.

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)

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

510(k) Number K050416