K042305

OCT 2 1 2004

# 510(K) Summary

A. Submitter Information

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|---|---|
| Submitter's Name: | OSSACUR® AG |
| Address: | Benzstrasse 2<br>D-71720<br>Oberstenfeld, Germany |
| Phone Number: | (+49) 70629404-0 |
| Fax Number: | (+49) 7062 9404-20 |
| Contact Person: | Arne Briest |
| Date of Preparation: | August 23, 2004 |

B. Device Name

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

C. Predicate Device

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|---|---|
| Trade Name: | Cerasorb® ORTHO (K014156) |

D. Device Description

*OSSAPLAST ORTHO* is a synthetic, implantable, resorbable, radiopaque β-tricalcium phosphate (β-TCP) ceramic in granulate form (particle size of 500 – 1000 µm). It consists of pure-phase β-TCP [$Ca_3(PO_4)_2$] and is osteoconductive, with high interconnecting porosity.

*OSSAPLAST ORTHO* 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 device.

F. Technological Characteristics Summary

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

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* 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2004

Ossacur AG
c/o Ms. Kristi M. Kistner, RAC
President
Pacific OtterWorks, Inc.
975 Veronica Springs Road
Santa Barbara, CA 93105

Re: K042305
OSSAPLAST® ORTHO
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: August 23, 2004
Received: August 25, 2004

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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K042305

Device Name: OSSAPLAST® ORTHO 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Mark N Milhern

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

**510(k) Number** K042305