MAR 8 2006

OSSACUR

K051047

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:	April 21, 2005

B. Device Name

Trade Name:	*COLLOSS™ E*
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:	OSSAPLAST™ ORTHO Bone Void Filler (K042305/K050416)
Trade Name:	HEALOS® II Bone Graft Substitute (K012751/K043308)
Trade Name:	Osteofil® DBM (K043420/K043421)
Trade Name:	InterGro® DBM (K031399)

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D. Device Description

COLLOSS E is a bone void filler extracted from the extracellular matrix of cortical diaphyseal equine bone. It is a lyophilizate in collagenous matrix form, consisting of collagen Type I chains with other insoluble proteins present.

COLLOSS E is dry with a cotton-like appearance, having a white to slightly yellowish color. The product is processed under aseptic conditions and is non-pyrogenic. It is supplied in a 20 mg quantity, packaged in a vial inside of a Tyvek pouch. The inner surfaces of the pouch are terminally sterilized by plasma sterilization.

E. Intended Use

COLLOSS E 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. *COLLOSS E* is resorbed and replaced with bone during the healing process.

F. Technological Characteristics Summary

COLLOSS E was characterized in accordance with *ASTM F 2212-02: Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPS).* The product description information and characterization data in conjunction with the device labeling demonstrate substantial equivalence to the predicate devices.

G. Performance Data

No performance standards have been established for this type of device. The results of animal testing demonstrated that *COLLOSS E* 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

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

Re: K051047/S1
Trade/Device Name: COLLOSS™ E 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: September 16, 2005
Received: September 19, 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 Mark N. Melkerson
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): _____

Device Name: COLLOSS™ E Bone Void Filler

Indications for Use:
COLLOSS E 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. COLLOSS E is 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 K051047