K021963

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 2 8 2003

1. GENERAL INFORMATION

Trade Name	BIOSORB® Resorbable Void Filler
Common Name	Resorbable Calcium Salt Bone Void Filler
Classification Name	Resorbable Calcium Salt Bone Void Filler
Class	Unclassified
Product Code	MQV
CFR section	888.3045
Device panel	Orthopedic
Special controls	As per 21 CFR 888.3045, the following special controls were established for Resorbable Calcium Salt Bone Void Filler: Draft Guidance for Resorbable Calcium Salt Bone Void Filler. FDA Guidance "Use of international standards Organization's ISO 10993 Biological evaluation of medical devices part I: Evaluation and testing" FDA Guidance "510(k) Sterility review Guidance – revision of 2/12/90 (K90-1)"
Performance Standard	ASTM F-1088-87 (reapproved 1992) "Standard specification for beta tricalcium phosphate for surgical implantation".
Submitter's name and address	Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES - FRANCE
Contact	Denis CLEMENT, General Manager Phone : 33 5 62 42 21 01 Fax : 33 5 62 42 21 00 e-mail : denis.clement.sr@wanadoo.fr

Summary preparation date: October 20, 2002

2. PREDICATE DEVICES

Trade Name	VITOSS scaffold synthetic cancellous bone void filler ® K 994337 PRO OSTEON 500R Resorbable Bone void filler K98017
Common Name	Resorbable Calcium Salt Bone Void Filler
Classification Name	Resorbable Calcium Salt Bone Void Filler
Class	unclassified
Product Code	MQV
CFR section	888.3045
Device panel	Orthopedic

3. DEVICE DESCRIPTION

BIOSORB ® is an osseo-conductive macroporous implant made of synthetic beta tri Calcium Phosphate (βTCP) indicated for Bone Void Filling.
BIOSORB® implants are available in various shapes and sizes in order to fill various bone defect. Shapes are basic such as granules, cylinders, blocks and cubes.
BIOSORB® presents a multidirectional interconnected porosity structure, similar to that of the human cancellous bone. BIOSORB® implant slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. The progressive resorption of BIOSORB® resorbable void filler is intended to prevent premature resorption.

4. INTENDED USE

BIOSORB® Resorbable Void Filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.
BIOSORB® Resorbable Void Filler does not possess sufficient mechanical strength to support reduction of a defect prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure rigid stabilization of the defect in all plans.

5. SAFETY AND EFFECTIVENESS TESTING SUMMARY

5.1 Biocompatibility

BIOSORB® conforms to the recognized consensus standard specification, ASTM F 1088-87 (reapproved 1992) for surgically implantable beta tricalcium phosphate. FDA has recognized the use of this consensus standard as verification of material characteristics and biocompatibility for surgical application (Recognition List Number 001, effective date: 19 feb 1998).
Moreover, the biocompatibility of βTCP implants is well documented. As a biomaterial β TCP has consistently proven to be non toxic, non allergenic, biocompatible and elicits no inflammation. No adverse system effects have been reported.
A wide variety of tests was performed on **BIOSORB** ®
According to ISO 10993 « Biologic evaluation of medical devices » and to the type of medical device (long-term implantable medical device, bone/tissue contact) the following biologic effects have been investigated:
Cytotoxicity, Sensitization, Genotoxicity and mutagenicity, Systemic toxicity, Irritation (intradermic injection), Systemic tolerance, Pyrogenicity
Testing performed on **BIOSORB** ® shows an excellent biocompatibility with no significant adverse observations of any kind.

5.2. Osseous rehabilitation

Histo-morphometric analyses were performed to estimate the percentage of osseous rehabilitation and the ingrowth depth within the pores of BIOSORB cylinders implanted in rabbit condyles up to four months. New bone formation is clearly evident by 4 weeks and a quasi complete (>90%) rehabilitation was observed by 10 weeks.

5.3. In vivo TCP dissolution

The evolution of the local calcium content around irradiated beta tricalcium phosphate ceramic implants has been evaluated in vivo (rabbit). Results indicate that part of the calcium dissolved from the implant is involved in a local mineralization process. The calcium of resorbable TCP implants represents a store which is probably involved in both local mineralization process during bone healing and circulating calcium pool, like physiological bone mineral.

5.4 Clinical data

A human clinical trial has been performed to investigate the safety and effectiveness of BIOSORB® bone void filler and more especially the achievement of a stable osseous fusion in consolidation of bone defects, the absence of inflammatory or septic response and the resorption of the BIOSORB ® implant and its replacement by osseous tissues.

Clinical and radiological data demonstrate the biocompatibility, the osseo integration and the resorption of BIOSORB ® bone void filler.

Several retrospective clinical studies have been published, supporting the use of BIOSORB beta-tricalcium phosphate ceramic (45% porosity – 250-400 µm pore-size).

- Use of β -tricalcium phosphate in foot and ankle surgery: a report of 20 cases in Foot and Ankle Surgery- Volume 7 (4)- 217 - December 2001.
- Filling of bone defects with tricalcium phosphate beta in traumatology. In Ann Chir 2000 Dec;125(10):972-81
- Beta-tricalcium phosphate ceramic as a bone substitute in orthopaedic surgery in Int Orthop 2002;26(2):109-15

6. SUBSTANTIAL EQUIVALENCE

Criteria	BIOSORB®	VITOSS®	PRO OSTEON®500
Indication	Synthetic bone void filler		
Intended use	To fill bony void or gaps of the skeletal system (i.e. the extremities, spine and pelvis) resulting from surgery or trauma that are not intrinsic to the stability of the bony structure.		
Labeling	Same intended use, contra-indications, warnings, precautions and adverse invents as predicate		
Chemical	Calcium salt		
Mineral phase	Beta Tri Calcium Phosphate $Ca_3(PO4)_2$	Beta Tri Calcium Phosphate $Ca_3(PO4)_2$	Calcium Carbonate Calcium Phosphate
Performance Std.	ASTM F1088-87	ASTM F1088-87	
Biocompatibility	Established		
Physical structure	Trabecular structure similar to cancellous bone		
Porosity	Interconnected porosity		

Criteria	BIOSORB®	VITOSS®	PRO OSTEON®500
	40-50% & 60-80%	88-92 %	55%
Pore size	250-400 µm	1-1000 µm	435 µm [280-779 µm]
Mechanical strength	Does not impart mechanical strength to surgical site		
Resorption	Resorbable		
	35% at 6 months and 72% at 12 months in human	Significantly by 3 months in human (76% at 6 weeks, 86% at 12 weeks in Canine)	About 6 months in human 20% at 6 weeks, 45% at 12 weeks in Canine)
Osseous Rehabilitation	Osseo-conductive		
	New bone formation clearly evident by 4 weeks and quasi complete (>90%) by 10 weeks (Rabbit)	New bone formation clearly evident by 6 weeks – complete by 12 weeks (Canine)	
Presentation	Various shapes - Various sizes		
Sterility	Sterilized by Gamma radiation Single use only		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Denis Clement
Genéral Manager
Sciences et Bio Matériaux (SBM)
Z.I. du Monge
65100 Lordes
France

JAN 28 2003

Re: K021963
Tade Name: BIOSORB® Resorbable Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: October 28, 2002
Received: October 30, 2002

Dear Mr. Clement:

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.

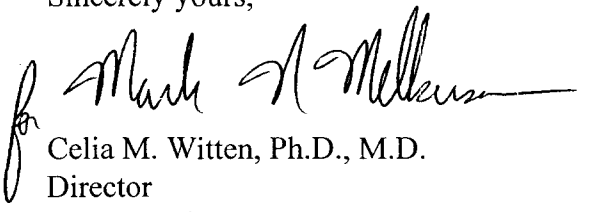
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

510(k) Number: K021963

Device Name : BIOSORB® RESORBABLE BONE VOID FILLER

Indications for Use:

BIOSORB® Resorbable Void Filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.
BIOSORB® Resorbable Void Filler does not possess sufficient mechanical strength to support reduction of a defect prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all plans.

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Mark N Milhem

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

510(k) Number K021963

Prescription Use _____ **or** **Over-the-Counter Use**
(PER 21 CFR 801.109)

(optional Format 1-2-96)