510 (k) Special Biosorb Bone Void Filler

SBM

510(K) SUMMARY

JUL 1 5 2013

1. GENERAL INFORMATION

Trade Name	BIOSORB RESORBABLE BONE VOID FILLER
Common Name	Bone void filler
Classification Name	Resorbable Calcium Salt Bone Void Filler device
Class	II
Product Code	MQV
CFR section	888.3045
Device panel	Orthopedic
Legally marketed predicate devices	BIOSORB RESORBABLE BONE VOID FILLER (K021963 and K071155)
Reason for special 510k	Extension of the range of products
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Owner operation Number : 9063735
Contact	Denis CLEMENT, General Manager Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact: anne.cospin@sbm-fr.com

2. DEVICE DESCRIPTION

BIOSORB bone void filler (K021963 and K071155) is an osseo-conductive macroporous implant made of synthetic beta tri Calcium Phosphate (βTCP) indicated for Bone Void Filling.
BIOSORB bone void filler presents a multidirectional interconnected porosity structure, similar to that of the human cancellous bone. BIOSORB bone void filler implant slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues.

To better fit the surgeon's needs and surgical preferences and patient's anatomy the full range of BIOSORB RESORBABLE BONE VOID FILLER will comprise:

- 9 shapes: stick, granule, cube, block (6 shapes)
- 3 material specifications: BIOSORB 30, BIOSORB 45 and BIOSORB 70
- 3 packaging: box, vial, syringe

The design modifications of the new NEOTIS set of wedges with respect to OTIS set of wedges include a sharper anterior area and a wider posterior area more fitting the natural tibia anatomy. 3 letters are printed to help the surgeon with the wedge orientation: A stands for Anterior, M stands for Medial and P for Posterior.
There are 50 NEOTIS parts instead of 10 OTIS parts, so that the range is increased.

3. INTENDED USE

BIOSORB Resorbable Bone 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, posterolateral spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure. BIOSORB Resorbable Bone 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.
In addition, when used with appropriate opening osteotomy system devices, plates and screws, BIOSORB Resorbable Bone Void Filler is intended to be used as a Bone void filler in Tibial Osteotomies.

4. PERFORMANCE DATA

BIOSORB bone void filler medical devices conform to Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA" established for Resorbable calcium salt bone void filler (21 CFR 888.3045).

The new implant design offers an enhanced anatomical fitting for HTO opening filling as verified by surgeons through cadaveric labs (RD837 – enclosed in Appendix 1).

5. SUBSTANTIAL EQUIVALENCE

The additional BIOSORB RESORBABLE BONE VOID FILLER products have the same fundamental scientific technology, operating principle and intended use as previously cleared BIOSORB RESORBABLE BONE VOID FILLER K021963 and K071155.

The design modification reduces the risk of inadequate filling of the HTO opening with concern to former wedges, and does not generate new risks. The device is as safe, as effective and performs as well as or better than the predicate BIOSORB RESORBABLE BONE VOID FILLER.

Summary preparation date: July 1, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

Science for Biomaterials
Sciences et Bio Matériaux
% Mr. Denis Clement
CEO
ZI du Monge
F 65100 LOURDES
FRANCE

Re: K130953
Trade/Device Name: BIOSORB Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 11, 2013
Received: June 17, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: BIOSORB Resorbable Bone Void Filler

Indications for Use:

BIOSORB Resorbable Bone 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, posterolateral spine and pelvis,) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure. BIOSORB Resorbable BoneVoid 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.

In addition, when used with appropriate opening osteotomy system devices, plates and screws, BIOSORB Resorbable Bone Void Filler is intended to be used as a bone void filler in tibial osteotomies.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130953