K033258

MAR - 9 2004

510(k) Summary: BoneSave™ Bone Void Filler

Proprietary Name:	BoneSave™ Bone Void Filler
Common Name:	Synthetic bone void filler
Classification Name and Reference:	Resorbable calcium salt bone void filler device 21 CFR 888.3045
Regulatory Class:	Class II
Device Product Code:	MQV – Filler, Calcium Sulfate, Preformed Pellet
Predicate Proprietary Name(s):	K991854: Osteoplast Bone Void Filler Pellets (Interpore Cross International) K020986: Mastergraft™ Resorbable Ceramic Pellets (Medtronic Sofamor Danek USA)
Predicate Regulatory Class:	Class II
Predicate Product Code(s):	MQV
Submitted By:	Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 (201) 825-4900
Contact Information:	Lorraine Montemurro Phone: (201) 831-5892 Fax: (201) 831-6038
Date Summary Prepared:	March 5, 2004

Description/Technological Comparison

Materials:

Both the subject device and the predicate Mastergraft™ Resorbable Ceramic Pellets (Medtronic Sofamor Danek) are granular bone void fillers consisting of TCP and HA. The subject device is 80wt.%TCP and 20wt.%HA, while the predicate device can be

either 60%HA/40%TCP or 15%HA/85%TCP. The TCP/HA ratio for the subject device falls in between the TCP/HA ratios cleared for the predicate device. Therefore, with regard to materials, the subject and predicate devices are substantially equivalent.

Intended Use:

The subject device and the predicate devices have the same intended use and indications for use. Therefore, with regard to intended use, the subject and predicate devices are substantially equivalent.

Design:

The subject and predicate devices are both available in granular (or "pellet") form. Therefore, with regard to design, the subject and predicate devices are substantially equivalent.

Intended Use

BoneSave™ Calcium phosphate granules (20cc) are indicated for osseous defect filling of bones not intrinsic to stability of the bony structure.

- BoneSave™ Calcium phosphate granules are indicated to be gently packed into osseous defects (i.e. bony voids or gaps) of the skeletal system (i.e., the extremities, spine, and pelvis).
- These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Testing Summary

Laboratory testing and animal testing were provided to characterize the subject device and to allow comparison of its characteristics to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Ms. Terry Sheridan Powell
Regulatory Affairs Team (Consultant)
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Re: K033258
Trade Name: BoneSave™ 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: February 17, 2004
Received: February 18, 2004

Dear Ms. Powell:

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,

for 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 (if known): K033258

Device Name: BoneSave™ Bone Void Filler

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Prescription Use ____X____ (Part 21 CFR 801 Subart D)	AND/OR	Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K033258