

AUG 26 1999

510(k) SUMMARY

K 551854

SUBMITTED BY

Lynn Rodarti
Manager, Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

(949) 453-3200

DATE: May 28, 1999

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Filler, Bone Void, Non-Osteoinductive
Common/Usual Name: Bone Void Filler, Bone Graft Substitute
Product Classification: Unclassified
Proprietary Name: Osteoplast Bone Void Filler

PREDICATE DEVICE

Wright Medical's OsteoSet Bone Void Filler 510(k) K963587 and 510(k) K963562.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS-FOR-USE

Osteoplast Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Osteoplast Bone Void Filler is indicated to be gently packed into 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. Osteoplast provides a bone void filler that resorbs and is replaced with bone during the healing process. Because Osteoplast is biodegradable and biocompatible, it may be used in an infected site.

DEVICE DESCRIPTION

Osteoplast Bone Void Filler is an osteoconductive calcium sulfate di-hydrate implant.

Osteoplast is comprised of a pre-measured formulation of calcium sulfate hemi-hydrate powder and accelerating saline solution. The powder and saline are combined to form calcium sulfate di-hydrate pellets, which are then gently packed into bony voids or gaps of the skeletal system. Osteoplast is supplied sterile for single use only. Calcium sulfate is an osteoconductive and biocompatible material which resorbs quickly in the human body as bony ingrowth occurs. The biodegradable, radiopaque material is resorbed in approximately 30-60 days when used according to labeling.

Osteoplast is an osteoconductive device. There are three prerequisites for osteoconduction and new bone formation to consistently occur:

1. There must be direct apposition of the implant to surrounding host bone. The implant must be within one to two millimeters of the host bone at all contact points. This is because bone cannot bridge a gap greater than one to two millimeters.
2. The host bone must be viable. That is, it must be normally functioning bone that is fully vascularized.
3. The interface between the host bone and implant must be stable, without macromotion.

These conditions are met when the defect is carefully reconstructed using Osteoplast, when the implant material is in direct apposition to viable bone, and when macromotion is minimized through the use of rigid fixation.

COMPARISON TO THE PREDICATE DEVICE

Osteoplast Bone Void Filler is substantially equivalent to the predicate device as a filler for non-loadbearing bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). In general, Osteoplast and OsteoSet are substantially equivalent in that they have identical Indications-For-Use. In addition, both are:

- Manufactured from Calcium sulfate
- Radiopaque
- Available sterile, off-the-shelf
- Inorganic/Synthetic
- Biocompatible
- Resorbable
- Used with rigid fixation
- Osteoconductive
- Osteophyllic
- Non toxic

In addition, both devices have similar mechanical compaction characteristics and both have similar use and handling characteristics.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

1. Contraindications:

This product is not intended to provide structural support during the healing process, therefore, Osteoplast is contraindicated where the device is intended as structural support in the skeletal system. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative disease
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instruction, including individuals who abuse drugs and/or alcohol.
- Hypercalcemia

2. Warnings and Precautions:

Osteoplast Bone Void Filler should not be mixed with other mixing solutions. To do so will alter the material's setting time and performance characteristics.

As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy or high dosage radiation therapy.

It is recommended that the treatment site be as dry and blood-free as possible. Gentle blotting with sterile gauze around, but not on, the treatment site may help to absorb excess blood or wetness. It is not recommended to use Osteoplast Bone Void Filler where severe bleeding is present. Severe bleeding may dislodge the material.

Osteoplast is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

Do not use this device if the ampule is cracked or broken.

3. Complications:

Possible adverse effects include but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complication that are possible with any surgery
- Fracture or extrusion of the Osteoplast pellets, with or without generation of particulate debris
- Deformity of the bone at the site

- Incomplete, or lack of osseous ingrowth into bone void, as is possible with any bone void filler

TESTING SUMMARY

Dissolution studies demonstrate that Osteoplast has dissolution rates which are substantially equivalent to the predicate device. Mechanical testing demonstrates that Osteoplast has compressive characteristics substantially equivalent to the predicate device. Testing indicates the product to be non-pyrogenic and non-toxic.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1999

Ms. Lynn Rodarti
Manager, Regulatory and Clinical Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K991854
Trade Name: Osteoplast, Model POP200
Regulatory Class: Unclassified
Product Code: MQV
Dated: May 28, 1999
Received: June 1, 1999

Dear Ms. Rodarti:

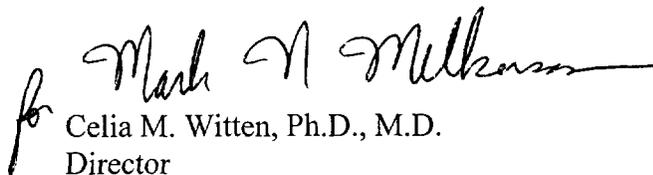
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

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

Enclosure

510(k) Number (if known): K 991854

Device Name: Osteoplast

Indications-For-Use:

Osteoplast Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Osteoplast Pellets are indicated to be gently packed into 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. The Pellets provide a bone void filler that resorbs and is replaced with bone during the healing process. Because the Pellets are biodegradable and biocompatible, it may be used at an infected site.

Mark A Melkerson

for
cmw

(Division Sign-Off)

Division of **General Restorative Devices**

510(k) Number

K991854

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)