

3/2/99

510(k) SUMMARY

K 990/31

SUBMITTED BY

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

(949) 453-3200

January 13, 1999

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Filler, Bone Void, Non-Osteoinductive
Common/Usual Name: Bone Graft Substitute, Bone Void Filler
Product Classification: Unclassified
Proprietary Name: Pro Osteon® 500R Resorbable Bone Graft Substitute

INDICATIONS-FOR-USE

Pro Osteon 500R Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Pro Osteon® 500R 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. The product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

Pro Osteon® 500R Resorbable Bone Graft Substitute is an osteoconductive porous implant similar in structure to human cancellous bone. It is supplied sterile in various shapes and sizes.

Pro Osteon® 500R has a trabecular structure that resembles the multidirectional interconnected porosity of cancellous bone. It has a median pore diameter of 435 microns. The implant is trabecular calcium carbonate covered by a very thin outer layer of calcium phosphate representing approximately 13% of the total implant structure. The calcium phosphate is located on the outer surface of the porosity throughout the entire structure of the implant. It is approximately 2 to 10 microns in thickness and overlays the calcium carbonate substructure. Once implanted, the calcium phosphate outer layer will slowly

resorb, delaying exposure of the underlying and faster resorbing calcium carbonate. Calcium carbonate resorption will normally occur within six months or less.

When Pro Osteon® 500R is placed in direct contact with viable bone, the reticulated spaces in the implant are infiltrated with tissue. Bone formation occurs in apposition to the Pro Osteon® 500R surface and within the interstices of the implant skeleton. As the implant resorbs, bone and soft tissue grow into the space previously occupied by the implant.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

1. Contraindications

Pro Osteon® 500R is contraindicated for fractures of the growth plate; for segmental defects; for indications which may be subjected to excessive impact or stresses; when there is significant vascular impairment proximal to the graft site; when there are metabolic or systemic disorders that affect bone or wound healing; when stabilization of the fracture is not possible; in cases where intraoperative soft tissue coverage is not planned or possible, and in infected sites.

2. Warning and Precautions

Pro Osteon® 500R does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure rigid stabilization of the defect in all planes. Pro Osteon® 500R Resorbable Bone Graft Substitute is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Complete postoperative wound closure is essential.

Pro Osteon® 500R is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

3. Potential complications using this device are the same as those encountered in autogenous bone grafting procedures and include the following: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1999

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

Re: K990131
Pro Osteon® 500R Resorbable Bone Graft Substitute
Regulatory Class: Unclassified
Product Code: MQV
Dated: January 13, 1999
Received: January 14, 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 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.

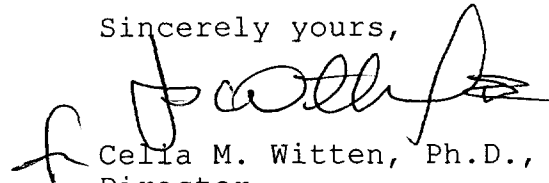
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 'C. Witten', with a stylized 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):

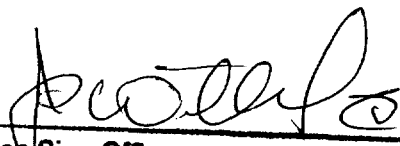
Device Name: Pro Osteon® Bone Graft Substitute

Indications-For-Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990131

Prescription Use X
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)