K993836

DEC 1 9 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Mary L. Verstynen

Product Code: LOD

Device Name: GENERATION 4 Bone Cement

Indications for Use:
GENERATION 4 Bone Cement is indicated for the fixation of prostheses to living bone in orthopedic musculoskeletal surgical procedures for osteoarthritis, rheumatoid arthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty procedures.

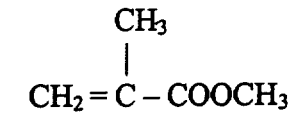
Device Description:
GENERATION 4 Bone Cement System is a self-curing agent comprised of two sterile components (liquid and powder) mixed in the Vacuum Pac delivery system forming polymethyl methacrylate (PMMA) bone cement.

The liquid component (monomer) is comprised of the following:

Methyl methacrylate monomer	98%
N,N-dimethyl-p-toluidine	2%
Hydroquinone	60ppm

Methyl methacrylate monomer is the primary constituent of the liquid component. In much smaller quantities are the accelerator, N,N-dimethyl-p-toluidine, and the stabilzer, hydroquinone, both of which are typical constituents in PMMA bone cement.

Formula:



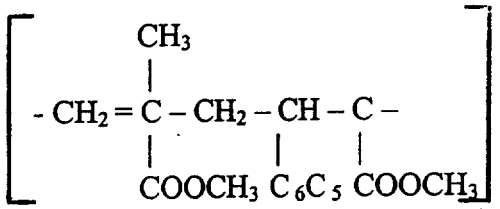
Methyl methacrylate monomer

The powder component is comprised of the following:

Methyl methacrylate – stryrene copolymer	90 %
Barium sulfate, U.S.P.	10%

Methyl methacrylate – styrene copolymer is the primary constituent of the powder component. Barium sulfate is added as a radiopacifier. Both are typical constituents of PMMA bone cement.

Formula:



Methyl methacrylate – styrene copolymer

When the powder and liquid components are mixed, the accelerator speeds the generation of free radicals and the stabilizer in the liquid reacts with many of the early free radicals, but is soon consumed. Free radicals can then initiate formation of polymer chains.

Polymerization proceeds slowly over the first few minutes. Polymer chains at the surface of the powder beads mingle with monomer and newly formed polymer chains, while smaller beads may dissolve completely. The cement temperature rises as set-time of the cement approaches. Polymerization is essentially complete and the bone cement hard within 10 minutes.

Potential Risks:

Cardiac arrest	Transitory fall in blood pressure
Myocardial infarction	Thromobophlebitis
Pulmonary embolism	Hemorrhage and hematoma
Cerebrovascular accident	Loosening or displacement of prosthesis
Sudden death	Superficial or wound infection
Trochanteric bursitis	Short-term cardiac conduction irregularities
Heterotopic new bone formation	Trochanteric separation
Pyrexia (due to allergy)	Hematuria
Dysuria	Bladder fisula
Local neuropathy	Local vascular erosion and occlusion

Intestinal obstruction due to extrusion of the bone cement beyond the region of its intended use

Substantial Equivalence: The GENERATION 4 Bone Cement was found to be substantially equivalent to the following predicate bone cement in terms of indications for use, intended use, technological characteristics and material.

Predicate device: Surgical Simplex P Radiopaque Bone Cement
Howmedica Corporation
PMA Number: N17004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Ms. Mary L. Verstynen
Manager of Clinical Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K993836
Trade Name: Generation 4® Bone Cement
Regulation Number: 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: II
Product Code: LOD
Dated: October 2, 2001
Received: October 3, 2001

Dear Ms. Verstynen:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K993836

DEVICE NAME: GENERATION 4 Bone Cement

INDICATIONS FOR USE:

GENERATION 4 Bone Cement is intended for the fixation of prostheses to living bone in orthopedic musculoskeletal surgical procedures for osteoarthritis, rheumatoid arthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty.

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

510(k) Number K993836

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

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over- The- Counter- No
(Optional Format 1-2-96