K052990 page 1 of 3

DEC 16 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lester F. Padilla

Proprietary Name: StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem

Common Name: Bone Cement Spacer Mold; Disposable Cement Spacer Molds for Temporary Hip Prosthesis

Classification Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360); Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Spacer-G Temporary Hip Prosthesis cleared by the FDA in K031841 and marketed in the US under the InterSpace™ Hip by Exactech, Inc., Gainesville, FL.

Device Description: The device consists of a sterile, assembled cement spacer mold made of medical grade silicone with a stainless steel reinforcement stem located inside the silicone mold, designed to construct a temporary cement hemi-hip femoral spacer. The silicone component of the spacer mold is designed to shape the temporary spacer but is not implanted, and is to be discarded after a single use. The stainless steel reinforcement stem serves as the load-bearing endoskeleton of the hemi-hip prosthetic implant and is incorporated into the prosthesis by being coated over by bone cement.

Polymethylmethacrylate/gentamicin bone cement is filled into the silicone mold containing the stainless steel reinforcement stem. The temporary hip prosthesis is removed from the silicone mold after the cement hardens and is placed into the patient's hip joint space.

The femoral cement spacer molds are offered in four sizes (9 mm x 125 mm/ 43mm head, 9 mm x 125 mm/ 51mm head, 13 mm x 145 mm/ 57 mm head & 17 mm x 165 mm/ 64 mm head).

Intended Use: The StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem is intended to provide the surgeon with a means to mold a temporary hemi-hip femoral prosthesis at the point of care, using a cleared polymethylmethacrylate/gentamicin bone cement. The predicate device is a temporary hemi-hip femoral prosthesis, made with

polymethylmethacrylate/gentamicin bone cement, pre-molded by the manufacturer.

Indication for Use: Disposable cement spacer molds with stainless steel reinforcements are intended to be used to mold a hemi-hip femoral prosthesis, indicated for temporary use (maximum 180 days) in skeletally mature patients undergoing a two-stage procedure due to septic process.

The temporary prosthesis is inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular implants and debridement. The temporary prosthesis is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-hip femoral prosthesis is not intended for use more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection, arthroplasty, fusion, etc.)

Because of inherent mechanical limitations of the material (polymethylmethacrylate/gentamicin), the molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

Contraindications:
The temporary hip prosthesis made with the disposable cement spacer molds is contraindicated for the following situations:

- The patient's condition is such that a two-stage arthroplasty procedure is contraindicated due to decreased immune response or other relevant systemic clinical conditions.
- Lack of adequate bone structure precludes adequate support of the prosthesis in the proximal femur or acetabular region.
- The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
- Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
- Infection of the THR cannot be confirmed.
- The infected THR devices cannot be removed.
- A systemic or secondary remote infection is expected or confirmed.
- The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
- The patient does not have a THR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis.
- The patient has neuromuscular disorders that do not allow control of the hip joint.

- The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
- The infecting pathogens are resistant to gentamicin.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Summary of Technologies: The bone cement molds are sterile disposables made of medical grade silicone with a reinforcement stem. The disposable cement spacer molds produce temporary hip prosthesis components that are composed of similar bone cement and reinforcement stems as the predicate.

Non-Clinical Testing: Comparative mechanical (fatigue) and antibiotic (gentamicin) elution testing was performed on both the temporary hip prosthesis made with the Biomet disposable cement spacer molds and the Exactech/Tecres Spacer-G predicate device. The temporary hip prostheses were found to be substantially equivalent in fatigue characteristics. The percentage of total gentamicin eluted from the spacer made from a Biomet mold and antibiotic-loaded G bone cement was substantially equivalent to the percentage of gentamicin eluted from the Tecres Spacer-G.

Clinical Testing: No clinical testing was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Lester F. Padilla
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K052990
Trade/Device Name: StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY, KWL
Dated: October 18, 2005
Received: October 24, 2005

Dear Mr. Padilla:

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) 594-4639. 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 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,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052990

Device Name: StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem

Indications For Use:
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- The patient does not have a THR and the infection is secondary to trauma, septic arthritis or other surgical procedures.

Mark N Milleson

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

510(k) Number K052990

Indications for Use

Biomet Manufacturing Corp.
Device Name: StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem

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- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis.
- The patient has neuromuscular disorders that do not allow control of the hip joint.
- The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
- The infecting pathogens are resistant to gentamicin.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K052990