K080979 P.1/2

BIOMET ORTHOPEDICS, INC.

OCT 31 2008

SECTION 5: 510(K) SUMMARY

Preparation Date: April 2, 2008

Applicant/Sponsor: Biomet Manufacturing Corporation

Contact Person: Gary Baker, MS RAC

Proprietary Name: StageOne™ Select Cement Spacer Molds for Temporary Hip Replacement.

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 § 888.3390 & 21 CFR § 888.3360).

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

StageOne™ Disposable Cement Spacer Mold (K052990) – Biomet Inc.
Tecres Spacer-G Temporary Hip Prosthesis (K031841) – Exactech Inc.

Device Description:

Cement Spacer Molds are designed to mold a temporary "spacer" hip implant made of antibiotic impregnated bone cement. The spacers are intended for short-term duration use only, not to exceed 6 months.

The StageOne™ Select Cement Spacer Molds are a series of Cement Spacer Molds designed to provide modularity of sizing between the femoral stem and the femoral head components. The molds provide various stem sizes and various head sizes that can be mated to provide the best fit for each patient. The cement spacer molds are made of biomedical grade silicone. The metal reinforcements within the cement spacer molds are made of implant grade stainless steel.

Indications for Use:

Disposable cement spacer molds with stainless steel reinforcement stems, adaptors and inserts are indicated for use to mold a temporary hemi-hip replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is assembled and inserted into the femoral medullary canal and

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

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

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

Summary of Technologies:

The StageOne™ Select Cement Spacer Molds are made of biomedical grade Silicone rubber, and are not to be implanted. The metal reinforcement stem within the femoral stem mold is made from 316 L Stainless Steel. The taper adapter and the head insert included within the head mold are made of implant grade 316 LVM Stainless Steel. The StageOne™ Select cement spacer molds use Cobalt G-HV Bone Cement cleared for marketing in K051532.

Non-Clinical Testing:

Cyclic fatigue testing was conducted on the StageOne™ Select components and the predicate StageOne™ components to provide a direct comparison of the subject and predicate components.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Biomet Manufacturing Corp.
% Mr. Gary Baker, MS RAC
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K080979
Trade/Device Name: Stageone™ Select Cement Spacer Molds for Temporary Hip Replacement
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY, KWL
Dated: October 22, 2008
Received: October 27, 2008

Dear Mr. Baker:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 4 - INDICATIONS FOR USE

510(k) Number (if known): K080979

Device Name: StageOne™ Select Cement Spacer Molds for Temporary Hip Replacement.

Indications for Use:

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

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

Neil R Ogden for mxm

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

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