



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 16, 2016

Biomet, Incorporated
Ms. Heidi Busz
Global Regulatory Affairs Associate
56 East Bell Drive
Warsaw, Indiana 46581

Re: K160071

Trade/Device Name: StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis

Regulation Number: 21 CFR 888.3027

Regulation Name: Polymethylmethacrylate (PMMA) bone cement

Regulatory Class: Class II

Product Code: MBB, HSD, KWS

Dated: April 15, 2016

Received: April 18, 2016

Dear Ms. Busz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K160071

Device Name
StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis

Indications for Use (Describe)

Disposable cement spacer molds are indicated for use to mold a temporary hemi-shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Palacos® R+G Bone Cement or Refobacin® Bone Cement R and inserted into the humeral medullary canal and glenoidal cavity following removal of the existing total shoulder replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-shoulder prosthesis made from the StageOne™ disposable cement molds 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-shoulder prosthesis material (Palacos® R+G Bone Cement and Refobacin® Bone Cement R), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitations throughout the implant period.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the StageOne™ Shoulder Spacer Molds 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

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Contact: Heidi Busz
 Regulatory Affairs Associate

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Date: May 31, 2016

Subject Device: **Trade Name:** StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis
Common Name: Bone Cement Shoulder Spacer Mold; Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis; StageOne™ Shoulder Spacer Mold

Classification Name:

- MBB-Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)
- HSD– Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)
- KWS-Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)

Legally marketed devices to which substantial equivalence is claimed:

- K131135-StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis
- K112983-Tecres S.p.A. InterSpace® Shoulder

Device Description

The single-use cement spacer molds are sterile disposables made of medical grade silicone. They are intended to be filled with Palacos® R+G Bone Cement or Refobacin® Bone Cement R by injecting with a dispenser/gun into the mold. After the cement cures, the hemi-shoulder prosthesis is to be removed from the mold and placed into the joint space. The hemi-shoulder prosthesis remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional shoulder joint prosthesis.

Indications for Use

Disposable cement spacer molds are indicated for use to mold a temporary hemi-shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Palacos® R+G Bone Cement or Refobacin® Bone Cement R and inserted into the humeral medullary canal and glenoidal cavity following removal of the existing total shoulder replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-shoulder prosthesis made from the StageOne™ disposable cement molds 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-shoulder prosthesis material (Palacos® R+G Bone Cement and Refobacin® Bone Cement R), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitations throughout the implant period.

Summary of Technological Characteristics

The subject modifications include the removal Cobalt™ G-HV Bone Cement from the Instructions for Use and the addition of Palacos® R+G Bone Cement and Refobacin® Bone Cement R for use with the subject device.

The subject modification does not result in any changes to the StageOne™ Shoulder Spacer Mold design features, materials, sizes, sterilization method, manufacturing process, sterility assurance level, or shelf life of the StageOne™ Shoulder Spacer Molds.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Mechanical performance testing and Gentamicin Elution testing of StageOne™ Shoulder Spacers fabricated with Palacos® R+G Bone Cement and Refobacin® Bone Cement R were compared to that of the predicate. The results demonstrated that StageOne™ Shoulder Spacers fabricated with Palacos® R+G Bone Cement and Refobacin Bone Cement R possess mechanical and elution characteristics comparable to those of the predicate device. Design validation test results confirm that the StageOne™ Shoulder Spacer Molds utilized with Palacos® R+G Bone Cement and Refobacin® Bone Cement R meet design requirements for use.
- Clinical Tests
 - Clinical data was not required to establish substantial equivalence between the subject StageOne™ Shoulder Spacer Molds and the predicate device.

Substantial Equivalence Conclusion

Based on the similarities in design, function, indications for use and fundamental scientific technology, the devices that are the subject of this submission are similar to the predicate devices and do not introduce any new risks of safety or efficacy. Therefore, Biomet concludes that the subject devices are substantially equivalent to the predicate devices.