DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 8, 2016

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

Re: K161166
Trade/Device Name: StageOne™ Select Disposable Cement Spacer Molds for Making Temporary Hemi-Hip Prosthesis with Reinforcement Stem
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MBB, KWY, KWL
Dated: August 2, 2016
Received: August 3, 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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

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

Indications for Use

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

510(k) Number *(if known)*

K161166

Device Name
StageOne™ Select Disposable Cement Spacer Molds for Making Temporary Hemi-Hip Prosthesis with Reinforcement Stem

Indications for Use *(Describe)*

Disposable cement spacer molds with stainless steel reinforcement stems, adapters 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 molded using PALACOS® R+G Bone Cement or Refobacin® Bone Cement R, assembled and inserted into the femoral medullary canal and 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 hemi-hip prosthesis made from the StageOne™ Select 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-hip prosthesis material (PALACOS® R+G Bone Cement and Refobacin® Bone Cement R), 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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™ Select Hip 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.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Heidi Busz
Regulatory Affairs Associate
Phone: 574-372-4249
Fax: 574-372-4710

Date: August 2, 2016

Subject Device: **Trade Name:** StageOne™ Select Cement Spacer Molds for Temporary Hip Replacement
Common Name: Bone Cement Spacer Mold; Disposable Cement Spacer Molds for Temporary Hip Prosthesis; StageOne™ Select Hip Spacer Molds

Classification Name:

- KWY– Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)
- KWL-Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360)
- MBB-Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)

Legally marketed devices to which substantial equivalence is claimed:

- K080979-StageOne™ Select Cement Spacer Molds for Temporary Hip Replacement

Device Description

The single-use cement spacer molds are sterile disposables made of medical grade silicone with a 316L stainless steel reinforcement stem. 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-hip prosthesis is to be removed from the molds with the reinforcement remaining as the core of the hemi-hip prosthesis, assembled using the neck length adapter and placed into the joint space. The hemi-hip prosthesis remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional hip joint prosthesis.

*Where available

Indications for Use

Disposable cement spacer molds with stainless steel reinforcement stems, adapters 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 molded using PALACOS® R+G Bone Cement or Refobacin® Bone Cement R*, assembled and inserted into the femoral medullary canal and 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 hemi-hip prosthesis made from the StageOne Select 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-hip prosthesis material (PALACOS® R+G Bone Cement and Refobacin® Bone Cement R*), 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 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™ Select Hip Spacer Mold design features, materials, sizes, sterilization method, manufacturing process, sterility assurance level, or shelf life of the StageOne™ Select Hip Spacer Molds.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Mechanical performance testing and Gentamicin Elution testing of StageOne™ Select Hip 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™ Select Spacers fabricated with PALACOS® R+G Bone Cement and Refobacin® Bone Cement R possess mechanical and elution characteristics equivalent to those of the predicate device. Bacterial endotoxin testing (BET) demonstrates that StageOne™ Select Hip Spacer Molds meet pyrogen limit specifications.
- Clinical Tests
  - Clinical data was not required to establish substantial equivalence between the subject StageOne™ Select Hip 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

*Where available

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.

*Where available