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

January 25, 2017

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

Re: K161273
Trade/Device Name: StageOne™ Disposable Cement Spacer Molds for Temporary Knee Prosthesis
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MBB, JWH
Dated: December 21, 2016
Received: December 22, 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)*

K161273

Device Name
StageOne™ Disposable Cement Spacer Molds for Temporary Knee Prosthesis

Indications for Use *(Describe)*

Disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (PALACOS® R+G Bone Cement and Refobacin® Bone Cement R), 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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™ Knee Spacer Mold 510(k) premarket notification. The submission was prepared as a Traditional 510(k) 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
574-372-4249
Fax: 574-372-4710

Date: June 24, 2016

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

Classification Name:
- MBB– Polymethylmethacrylate (PMMA) bone cement, antibiotic (21 CFR 888.3027)
- JWH – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

Legally marketed devices to which substantial equivalence is claimed:
- K050210 – Disposable Cement Spacer Molds for Temporary Knee Prosthesis

Device Description
The disposable cement spacer molds (femoral and tibial) 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*, either by injecting with a dispenser/gun, or by pouring the prepared cement into the mold. After the cement cures, the temporary spacers are to be removed from the molds and placed into the joint space. The spacers remain in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional knee joint prosthesis.

Indications for Use
Disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of

180 days or less. Because of inherent mechanical limitations of the device material (PALACOS® R+G Bone Cement and Refobacin® Bone Cement R*), 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.

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™ Knee Spacer Mold design features, materials, sizes, sterilization method, manufacturing process, sterility assurance level, or shelf life of the StageOne™ Knee Spacer Molds.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Mechanical performance testing and Gentamicin Elution testing of StageOne® Knee Spacers fabricated with PALACOS® R+G Bone Cement and Refobacin® Bone Cement R was conducted. The results demonstrated that StageOne® Knee 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.
- Clinical Tests
  - Clinical data was not required to establish substantial equivalence between the subject StageOne™ Knee Spacer Molds and the predicate device.

Substantial Equivalence Conclusion

Based on predicate and the subject devices being the same in design, function, fundamental scientific technology, and very similar in indications for use, the subject devices are very 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.

*Where available