December 28, 2022

Biomet, Inc.
Meredith Reed
Regulatory Affairs Senior Specialist
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581

Re: K222760
Trade/Device Name: StageOne™ Select Hip Cement Spacer Molds
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: MBB, KWY, KWL
Dated: December 1, 2022
Received: December 5, 2022

Dear Meredith Reed:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose -S

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222760

Device Name
StageOne™ Select Hip Cement Spacer Molds

Indications for Use *(Describe)*
StageOne™ Select Hip 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 Refobacin Bone Cement R, assembled and inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular 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-hip prosthesis made from the StageOne™ Select Cement Spacer 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 (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.

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 Cement 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 September 13, 2019.

Sponsor:

Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581, USA
Establishment Registration Number: 1825034

Contact Person:

Meredith Reed
Regulatory Affairs Senior Specialist
Telephone: (574) 209-6028

Date:

27 December 2022

Subject Device:

Trade Name: StageOne™ Select Hip Cement Spacer Molds
Common Name: Temporary Bone Cement Hemi-Hip Prosthesis
Classification Name:

- MBB – Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)
- KWY – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented (21 CFR 888.3390)
- KWL – Prosthesis, Hip, Hemi-, Femoral, Metal (21 CFR 888.3360)

Predicate Device:

K161166	StageOne™ Select Disposable Cement Spacer Molds for Making Temporary Hemi-Hip Prosthesis with Reinforcement Stem	Biomet, Inc.

Reference Device:

K080979	StageOne™ Select Cement Spacer Molds for Temporary Hip Replacement	Biomet, Inc.

Purpose and Device Description:

The purpose of this submission is to obtain clearance for the proposed modifications to the manufacturing process, sterile packaging configuration, product labeling including adding MR Unsafe labeling, engineering drawings and indications for use regarding bone cement marketed for use with the StageOne™ Select Hip Cement Spacer Molds.

The StageOne™ Select Hip Cement Spacer Molds are sterile, single use medical devices made of silicone with a stainless steel reinforcement stem, head insert and neck length adapter. The device is used to create a temporary hip implant component made from antibiotic bone cement, Refobacin® Bone Cement R by injecting with a dispenser/gun into the mold. After removal of the initial femoral and acetabular implants, the prepared cement spacers are assembled using the neck length adapter and placed into the femoral joint space using Refobacin® Bone Cement R as the first stage of a two-stage revision surgical procedure. The temporary hemi-hip prosthesis remains in place (180 days or less) until the second stage of the two-stage revision procedure is performed to implant a conventional hip joint prosthesis.

Intended Use:

The StageOne™ Select Hip Cement Spacer Molds are intended to create a temporary hemi-hip replacement prosthesis as part of a two-stage revision procedure.

Indications for Use:

StageOne™ Select Hip 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 Refobacin Bone Cement R, assembled and inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular 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-hip prosthesis made from the StageOne™ Select Hip Cement Spacer 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 (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 rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical to the predicate device.
- **Indications for Use:** The subject device has similar indications for use as the identified predicate device. Subject device is now only indicated for use with Refobacin® Bone Cement R cleared under K171540. There are no changes to the intended clinical use of the device.

- **Materials:** The subject device is made of the same raw materials as the identified predicate device.
- **Design Features:** The subject device has the same design features as the identified predicate device.
- **Variants/Sizes:** The subject device has the same variants and sizes as the identified predicate device.
- **Sterilization:** Identical to the predicate device.
- **Packaging:** The subject device has similar packaging to the predicate device. Both the subject and predicate devices are packaged using a double sterile barrier configuration.
- **Manufacturing Process:** The subject device is manufactured using a manufacturing process similar to the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Testing:** Non-clinical performance testing was conducted to support the proposed modifications for the subject StageOne Select Hip Cement Spacer Molds and establish substantial equivalence between the subject device and the identified predicate.
  - Biocompatibility Evaluation
  - Packaging testing
  - Shelf-life testing
  - Sterilization Validation
  - Magnetic Resonance Imaging (MRI) Analysis
  - Fatigue performance testing
  - Antibiotic elution testing
  - BET and pyrogenicity testing

- **Clinical Testing:** Clinical data and conclusions were deemed not necessary to establish substantial equivalence between the subject StageOne Select Hip Cement Spacer Molds and the identified predicate for the proposed device modifications.

Substantial Equivalence Conclusion:

The subject device has the same intended use, similar clinical indications for use as the predicate device. There are no changes to the design features, materials, operating principle, shelf-life or sterilization method. Except for the modifications described in this submission the subject device is identical to the predicate device, and the performance data and analyses demonstrate that:

- Any differences do not raise new questions of safety and effectiveness; and
- The proposed device is at least as safe and effective as the legally marketed predicate device.