September 15, 2022

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

Re: K221968
Trade/Device Name: StageOne™ Shoulder Cement Spacer Molds
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: MBB, HSD, KWS
Dated: July 1, 2022
Received: July 5, 2022

Dear Neha Sreenath:

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,

For

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)*
K221968

Device Name
StageOne™ Shoulder Cement Spacer Molds

Indications for Use *(Describe)*
StageOne™ Shoulder 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 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 StageOne™ Shoulder 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-shoulder prosthesis material (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.

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™ Shoulder 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:

Neha Sreenath
Regulatory Affairs Senior Specialist
Telephone: (0065-8504 1704)

Date:

01 July 2022

Subject Device:

Trade Name: StageOne™ Shoulder Cement Spacer Molds
Common Name: Temporary Bone Cement Hemi-Shoulder Prosthesis
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)

Predicate Device:

K160071	StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis	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, engineering drawings and indications for use regarding bone cements marketed for use with the StageOne™ Shoulder Cement Spacer Molds.

The subject device is a sterile, single use device made of silicone and is used to create a temporary hemi-shoulder implant component made from antibiotic bone cement, Refobacin® Bone Cement R. After removal of the initial implant the prepared cement spacer is placed into the glenohumeral joint space using Refobacin® Bone Cement R as the first stage of a two-

stage revision surgical procedure. The temporary spacer remains in place (180 days or less) until the second stage of the two-stage revision procedure is performed to implant a conventional shoulder joint prosthesis.

Intended Use:

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

Indications for Use:

StageOne™ Shoulder 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 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 StageOne™ Shoulder 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-shoulder prosthesis material (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 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 predicate device. The subject device is now indicated for use only with Refobacin® Bone Cement R. 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 predicate device.
- **Design Features:** The subject device has the same design features as the predicate device.
- **Variants/Sizes:** The subject device has the same variants and sizes as the predicate device.
- **Sterilization Method:** 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.

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™ Shoulder Cement Spacer Molds and establish substantial equivalence between the subject device and the identified predicate.
  - Biocompatibility Evaluation
  - Packaging testing
  - Sterilization Validation
  - Fatigue performance testing
  - Static performance testing
  - Antibiotic elution testing

- **Clinical Testing:** Clinical data and conclusions were deemed not necessary to establish substantial equivalence between the subject StageOne™ Shoulder 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. The proposed device has similar technological characteristics to the predicate device, and the information provided herein demonstrates 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.