



September 2, 2022

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

Re: K213287

Trade/Device Name: StageOne™ Knee Cement Spacer Molds  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement  
Regulatory Class: Class II  
Product Code: MBB, JWH  
Dated: August 5, 2022  
Received: August 8, 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/pmnmn.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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2023  
See PRA Statement below.

### Indications for Use

510(k) Number (if known)  
K213287

Device Name  
StageOne™ Knee Cement Spacer Molds

Indications for Use (Describe)

StageOne™ Knee Cement Spacer Molds are indicated for use to mold a temporary total knee replacement (TKR) 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 joint space following removal of the existing total knee replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The knee prosthesis made from the StageOne™ Knee 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 knee prosthesis material (Refobacin® Bone Cement R), the temporary knee prosthesis is only indicated for patients who will consistently use traditional mobility 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™ Knee 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 6854 7227)

**Date:** August 31, 2022

**Subject Device:** **Trade Name:** StageOne™ Knee Cement Spacer Molds  
**Common Name:** Temporary Bone Cement Knee Prosthesis  
**Classification Name:**

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

**Predicate Device:**

K161273	StageOne Disposable Cement Spacer Molds for Temporary Knee Prosthesis	Biomet, Inc.
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**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 Knee Cement Spacer Molds.

The subject device is a sterile, single use device made of silicone and is used to create temporary tibial and femoral implant components made from antibiotic bone cement, Refobacin® Bone Cement R. After removal of the initial implant the prepared cement spacers are placed into the tibiofemoral joint space using Refobacin® Bone Cement R as the first stage of a two-stage revision surgical procedure. The temporary spacers remain in place (180 days or less) until the second stage of the two-stage revision procedure is performed to implant a conventional knee joint prosthesis.

**Intended Use:** The StageOne Knee Cement Spacer Molds are intended to create a temporary knee replacement prosthesis as part of a two-stage revision procedure.

**Indications for Use:** StageOne™ Knee Cement Spacer Molds are indicated for use to mold a temporary total knee replacement (TKR) 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 joint space following removal of the existing total knee replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The knee prosthesis made from the StageOne™ Knee 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 knee prosthesis material (Refobacin® Bone Cement R), the temporary knee prosthesis is only indicated for patients who will consistently use traditional mobility 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 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:** The subject device is sterilized using the same sterilization method as the predicate device.
- **Manufacturing Process:** The subject device is manufactured using a manufacturing process similar to the predicate device.
- **Packaging:** The subject device has similar packaging as the predicate device; both the subject and predicate devices are packaged in a double sterile barrier configuration.

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

- **Non-Clinical Testing:** Nonclinical performance testing was conducted to support the proposed modifications for the subject StageOne™ Knee Cement Spacer Molds and establish substantial equivalence between the subject device and identified predicate device.
  - Biocompatibility Evaluation
  - Packaging testing
  - Sterilization Validation
  - Wear testing
  - Antibiotic elution testing
  
- **Clinical Testing:** Clinical data was not required to establish substantial equivalence between the subject StageOne Knee Cement Spacer Molds and the identified predicate device 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.