November 20, 2024

Osartis GmbH
Stefan Deußer
Director Research & Development
Auf der Beune 101
Munster, 64839
Germany

Re: K240856
Trade/Device Name: Hip Spacer Molds; Knee Spacer Molds; Shoulder Spacer Molds
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: MBB, KWL, KWY, HSD, KWS, JWH
Dated: March 27, 2024
Received: March 28, 2024

Dear Stefan Deußer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.11.20 12:56:23 -05'00'

Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240856

Device Name

Hip Spacer Molds;
Knee Spacer Molds;
Shoulder Spacer Molds

Indications for Use *(Describe)*

Hip Spacer Molds
Hip Spacer Molds with stainless-steel reinforcement stems, centralizers and Hip Head Inserts are indicated for use to mold a temporary hemi-hip spacer for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary hemi-hip spacer is molded using Cemex Genta LV, and inserted into 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 antibiotic therapy (standard treatment approach to an infection).
The temporary hemi-hip spacer made from Hip 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 temporary hemi-hip spacer material (Cemex Genta LV) the temporary hemi-hip spacers is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.

Knee Spacer Molds
Femoral Knee Spacer Molds and Tibial Knee 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 Cemex Genta LV 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 temporary total knee spacer made from the Femoral Knee Spacer Molds and Tibial Knee 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 temporary total knee spacer material (Cemex Genta LV), the temporary total knee spacer is only indicated for patients who will consistently use traditional mobility devices (e.g., crutches, walkers) throughout the implant period.

Shoulder Spacer Molds
Shoulder Spacer Molds with stainless-steel reinforcement stems, centralizers and Shoulder Head Inserts are indicated for use to mold a temporary hemi-shoulder spacer for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary hemi-shoulder spacer is molded using Cemex Genta LV, and inserted into 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 antibiotic therapy (standard treatment approach to an infection).
The temporary hemi-shoulder spacer made from Shoulder 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 hemi-shoulder prothesis material (Cemex Genta LV) the temporary hemi-shoulder prothesis 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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"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 the following information is provided for the Spacer Molds.

General Information

Date of preparation	October 21, 2024
Submission type	Traditional 510(k)
Submitter and Owner 510(k):	OSARTIS GmbH Auf der Beune 101 64839 Münster Germany Phone: +49 6071 / 929-0 Fax: +49 6071 / 929-100
Contact Person:	Volker Stirnal

Device Name

Trade Name:	Hip Spacer Molds Knee Spacer Molds Shoulder Spacer Molds
Common/Usual Name:	Bone Cement Spacer Mold; Disposable Cement Spacer Molds for Temporary Hemi-Hip, Knee and Hemi-Shoulder Prosthesis

Classification Information

Classification Name:	Bone cement, Antibiotic, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis,
Classification Regulation:	21 CFR § 888.3027, § 888.3360, § 888.3390
Regulatory Class:	Class II
Product Code:	MBB
Subsequent Product Codes:	KWL, KWY
Panel:	Orthopedic

510(k) Summary

Classification Name:	Bone cement, Antibiotic; Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer,
Classification Regulation:	21 CFR § 888.3027, § 888.3560
Regulatory Class:	Class II
Product Code:	MBB
Subsequent Product Code:	JWH
Panel:	Orthopedic

Classification Name:	Bone cement, Antibiotic, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, Shoulder joint metal/polymer semi-constrained cemented prosthesis,
Classification Regulation:	21 CFR § 888.3027, § 888.3690, § 888.3660,
Regulatory Class:	Class II
Product Code:	MBB
Subsequent Product Codes:	HSD, KWS
Panel:	Orthopedic

Predicate Device

- REMEDY® Hip and Knee Spacer (K112470) – Originally cleared under the trade name, 2GC Hip/Knee Modular Spacer (S.E. 04/05/2012)
- Remedy® Shoulder Spacer (K152267, S.E. 12/15/2015)
- InterSpace Knee (K181732, S.E. 27/04/2019)

Reference Device

- Biomet OneStage Hip Spacer Mold K222760
- Biomet OneStage Knee Spacer Mold K213287
- Biomet OneStage Shoulder Spacer Mold K221968

Device Description

Hip Spacer Molds

The Hip Spacer Molds are sterile, single use molds used for forming of interim prothesis from bone cement. These interim prothesis are intended as temporary hemi-hip spacers in a two-stage septic hip joint endoprosthesis. The Hip Spacer Molds are available as modular system, which is combinable to obtain different sized spacers.

Knee Spacer Molds

The Femoral and Tibial Knee Spacer Molds are sterile, single use molds used for forming of interim prothesis from bone cement. These interim prothesis are intended as temporary knee spacers in a two-stage septic knee joint endoprosthesis. The Knee Spacer Molds are available as modular system, which is combinable to obtain different sized spacers.

510(k) Summary

Shoulder Spacer Molds

The Shoulder Spacer Molds are sterile, single use molds used for forming of interim prothesis from bone cement. These interim prothesis are intended as temporary hemi-shoulder spacers in a two-stage septic glenohumeral joint endoprosthesis. The Shoulder Spacer Molds are available as modular system, which is combinable to obtain different sized spacers.

Indication for Use

Hip Spacer Molds

Hip Spacer Molds with stainless-steel reinforcement stems, centralizers and Hip Head Inserts are indicated for use to mold a temporary hemi-hip spacer for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary hemi-hip spacer is molded using Cemex Genta LV, and inserted into 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 antibiotic therapy (standard treatment approach to an infection).
The temporary hemi-hip spacer made from Hip 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 temporary hemi-hip spacer material (Cemex Genta LV) the temporary hemi-hip spacers is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.

Knee Spacer Molds

Femoral Knee Spacer Molds and Tibial Knee 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 Cemex Genta LV 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 temporary total knee spacer made from the Femoral Knee Spacer Molds and Tibial Knee 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 temporary total knee spacer material (Cemex Genta LV), the temporary total knee spacer is only indicated for patients who will consistently use traditional mobility devices (e.g., crutches, walkers) throughout the implant period.

510(k) Summary

Shoulder Spacer Molds

Shoulder Spacer Molds with stainless-steel reinforcement stems, centralizers and Shoulder Head Inserts are indicated for use to mold a temporary hemi-shoulder spacer for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary hemi-shoulder spacer is molded using Cemex Genta LV, and inserted into 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 antibiotic therapy (standard treatment approach to an infection).
The temporary hemi-shoulder spacer made from Shoulder 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 hemi-shoulder prothesis material (Cemex Genta LV) the temporary hemi-shoulder prothesis is only indicated for patients who will consistently follow activity limitations throughout the implant period.

Comparison of the indication for use with the predicate device

The new molds and the predicate spacers share the same primary function, mode of action, target patient population, conditions of use and use in the same surgical procedure, users and body contact. Both the new molds and the predicate spacers have the same intended use: to provide patients undergoing the first stage of a two-stage revision procedure a temporary joint implant to allow partial weightbearing, flexibility and mobility while the infection is treated. The slight differences in the indication for use statement focus on the different technological characteristics of providing a mold to fabricate the spacer versus providing a prefabricated spacer.

Comparison of the technological Characteristics with the Predicate Device

The produced interim hemi-hip, knee and hemi-shoulder spacer, which are molded with the Hip, Knee and Shoulder Spacer Molds have the same technological characteristics compared to the predicate devices (K112470, K152267, K181732).
Performance testing was performed to demonstrate substantial equivalence of the subject devices with the predicate devices.

Summary of Performance Data

The collection of performance data was conducted according to FDA recognized standards in order to demonstrate substantial equivalence to the predicate devices.

Sterilization and Shelf life: The sterilization process, including the ethylene oxide method has been validated and the sterility of the subject devices has been verified according to ISO 11135. The Spacer Molds have a shelf life of 2 years.

Biocompatibility: The Hip Spacer Molds, Knee Spacer Molds, and Shoulder Spacer Molds have been categorized for their body contact and duration of contact according to ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process" to select the appropriate biocompatibility testing program.

Hip Spacer Molds
According to ISO 10993-1, the Hip Spacer Molds is categorized as an Implant Device in indirect contact with Tissue/Bone for more than 30 days (>30 days: Permanent device), Exposure Category: C.

510(k) Summary

Knee Spacer Molds
According to ISO 10993-1, the Knee Spacer Molds is categorized as an Externally Communicating Device in indirect contact with Tissue/Bone for less than 24 hours (<24 hours: limited contact device), Exposure Category: A.

Shoulder Spacer Molds
According to ISO 10993-1, the Hip Spacer Molds is categorized as an Implant Device in indirect contact with Tissue/Bone for more than 30 days (>30 days: Permanent device), Exposure Category: C.

Therefore, the following tests were performed:
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous reactivity (ISO 10993-23)
- Pyrogenicity (ISO 10993-11)
- Acute systemic toxicity (ISO 10993-11)

Performance testing: The following tests were performed.

- Endurance properties and performance requirements of stemmed femoral hip components according to ISO 7206-4
- Endurance properties and performance requirements of neck region stemmed femoral hip components according to ISO 7206-6
- Wear of total knee-joint prothesis according to ISO 14243-1
- Endurance properties of tibial trays according to ASTM F1800
- Endurance properties of the stem and neck region of molded shoulder spacer based on ISO 7206-4 and ISO 7206-6
- Antibiotic (gentamicin) elution testing

Conclusion

The Hip Spacer Molds, the Knee Spacer Molds as well as the Shoulder Spacer Molds have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subjects and predicate devices.