August 2, 2024

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Julia Bally
Regulatory Affairs Senior Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K241716
Trade/Device Name: Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee Component
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO, LPH, LZO
Dated: June 14, 2024
Received: June 14, 2024

Dear Julia Bally:

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.

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K241716

Device Name

Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee Component

Indications for Use *(Describe)*

Indications for the MRS Stems and Intercalary Stems presented in K952970:

This device is intended for use in patients requiring extensive reconstruction of the femur and/or proximal tibia, including the hip or knee joint, resulting from extensive bone loss. Tumor resection for skeletal lesions (Oncology patients where radical bone resection and replacement may be required), revision surgery for failed arthroplasty, and acute trauma are the primary causes of extensive bone loss. These prostheses are intended for use with bone cement.

The Intercalary System is intended for use in situations arising from in femoral mid-shaft tumor resection, or for prosthetic knee fusion.

Indications for the Global Modular Replacement System (presented in K023087):

Femoral and/or proximal tibial replacement and total femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

Indications for the GMRS Anteverted Proximal Femoral Component (presented in K032581):

Femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This component may also be used with the Distal Femoral segment components of the GMRS in total femoral replacement.

Indications for the Global Modular Replacement System Press Fit Stems with HA Coating (presented in K022403, and K031217):

Proximal femoral reconstruction secondary to:

- o Trauma
- o Failed previous prosthesis
- o Tumor resection

Indications for the Modular Replacement System Cemented Stems (presented in K040749):

Femoral and/or proximal tibial replacement due to:

o Trauma

o Failed previous prosthesis

o Tumor resection

Indications for the Modular Rotating Hinge Knee System (cleared in K002552)

The Modular Rotating Hinge Knee System is intended for use with bone cement in cases where there is destruction of the joint surfaces, with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; the ligaments are inadequate and/or the musculature is weak; and revision of a failed previous prosthesis where there is instability, with or without bone loss or inadequate soft tissue.
Expanded indications include for use with bone cement in situations where there is extensive bone loss, including limb salvage procedures for severe trauma, failed previous prosthesis, and/or Oncology indications.

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.***

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# 510(k) Summary

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**Date Prepared**: 14-June-2024

**Proprietary Name:** Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee Component

**Common Name**: Hip Replacement, Rotating Hinge Knee Replacement

**Classification Name:** Hip joint metal/polymer semi-constrained cemented prosthesis. (21 CFR § 888.3350)
Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR § 888.3510)
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR § 888.3358)
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.( 21CFR § 888.3353)

**Product Codes:** JDI, KRO,LPH, LZO

**Primary Predicate Device to Which Substantial Equivalence is Claimed:**
Submission Number: K222056
Device Name: Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee
Product Codes: JDI, KRO, LPH, LZO

**Additional Predicate Device Used to Support Substantial Equivalence:**

| Submission Number | Device Name | Product Codes |
|---|---|---|
| K233261 | Global Modular Replacement System | JDI, KRO, LPH |
| K023087 | Global Modular Replacement System | KRO, JDI |
| K952970 | Modular Replacement System | JDI, KRO |
| K032581 | GMRS Anteverted Proximal Femoral Component | LPH |
| K040749 | Modular Replacement System Cemented Stems | KRO |
| K022403 | GMRS PRESS FIT STEMS WITH PUREFIX HA | LZO |
| K031217 | GMRS PRESS FIT STEMS WITH PUREFIX HA | LZO |
| K002552 | HOWMEDICA OSTEONICS MODULAR ROTATING HINGE KNEE | KRO |

**Reason for 510(k) Submission:**

The purpose of this "Change Being Effected" bundled submission is to add a contraindication to the labeling of the subject Global Modular Replacement System, Modular Replacement System, and Modular Rotating Hinge Knee Component. Additionally, MRI Safety information is being updated to align with the example labeling provided in the FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" (dated October 10, 2023), and clerical updates are also being made to the IFUs.

**Device Description:**

The Global Modular Replacement System (GMRS) is comprised of a number of components that are intended to be used in conjunction with each other, or in conjunction with components of the Modular Replacement System (MRS) or the Modular Rotating Hinge Knee System (MRH). The Modular Rotating Hinge Knee System is a tricompartmental knee system. The system consists of a stemmed femoral component and a stemmed tibial bearing component connected by a set of bushings and an axle. The MRH Tibial Rotating component is a part of the MRH system and mates with the GMRS Standard Proximal Tibia. These devices are intended to be used in clinical situations where there is radical bone loss of the femur and/or proximal tibia. This radical bone loss can be related to oncology (tumor), trauma or failed previous prosthesis.

**Intended Use:**
The Stryker Global Modular Replacement System, Modular Replacement System and Modular Rotating Hinge Knee Component are sterile, single-use devices
intended for use in situations where there is a need for replacement of bone due to radical bone

loss. This loss can be related to oncology, trauma or failed previous prosthesis.
Specific Indications for Use are listed below.

**Indications:**
Indications for the MRS Stems and Intercalary Stems (presented in K952970):

- This device is intended for use in patients requiring extensive reconstruction of the femur and/or proximal tibia, including the hip or knee joint, resulting from extensive bone loss. Tumor resection for skeletal lesions (Oncology patients where radical bone resection and replacement may be required), revision surgery for failed arthroplasty, and acute trauma are the primary causes of extensive bone loss. These prostheses are intended for use with bone cement.
- The Intercalary System is intended for use in situations arising from femoral mid-shaft tumor resection, or for prosthetic knee fusion.

Indications for the Global Modular Replacement System (presented in K023087):

- Femoral and/or proximal tibial replacement and total femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

Indications for the GMRS Anteverted Proximal Femoral Component (presented in K032581):

- Femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This component may also be used with the Distal Femoral segment components of the GMRS in total femoral replacement.

Indications for the Global Modular Replacement System Press Fit Stems with HA Coating (presented in K022403, and K031217):

- Proximal femoral reconstruction secondary to:
  o Trauma
  o Failed previous prosthesis
  o Tumor resection

Indications for the Modular Replacement System Cemented Stems (presented in K040749):

- Femoral and/or proximal tibial replacement due to:
  o Trauma
  o Failed previous prosthesis
  o Tumor resection

Indications for the Modular Rotating Hinge Knee System (presented in K002552):

- The Modular Rotating Hinge Knee System is intended for use with bone cement in cases where there is destruction of the joint surfaces, with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; the ligaments are inadequate and/or the musculature is weak; and revision of a failed previous prosthesis where there is instability, with or without bone loss or inadequate soft tissue.
  Expanded indications include for use with bone cement in situations where there is extensive bone loss, including limb salvage procedures for severe trauma, failed previous prosthesis, and/or Oncology indications.

**Summary of Technological Characteristics:**

Technological characteristics of the subject devices are identical to those of the predicate devices identified in this submission. The labeling updates in this submission have no impact on the technological characteristics of the subject and predicate devices.

**Non-Clinical Testing:**

Non-Clinical testing was not required as a basis for substantial equivalence.

**Clinical Testing:**

Clinical testing was not required as a basis for substantial equivalence.

**Conclusion:**
Based upon a comparison of the intended use, indications for use, design, materials, sterilization, technological characteristics, and operational principles, the subject devices are substantially equivalent to the predicate devices identified in this premarket notification.