January 26, 2023

Howmedica Osteonics Corp., dba Stryker Orthopaedics
Margaret Klippel
Chief Regulatory Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K222056
Trade/Device Name: Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO, LZO, LPH
Dated: January 13, 2023
Received: January 17, 2023

Dear Margaret Klippel:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222056

Device Name
MRS Stems and Intercalary Stems

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.

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)

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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)*

K222056

Device Name
Global Modular Replacement System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

[x] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222056

Device Name
GMRS Press Fit Stems with HA Coating

Indications for Use *(Describe)*
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

Type of Use *(Select one or both, as applicable)*

[x] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K222056

Device Name
GMRS Anteverted Proximal Femoral Component

Indications for Use *(Describe)*
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.

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)

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222056

Device Name
MRS System Cemented Stems

Indications for Use *(Describe)*

Indications for the Modular Replacement System Cemented Stems (cleared in K040749):
Femoral and/or proximal tibial replacement due to:
o Trauma
o Failed previous prosthesis
o Tumor resection

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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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)*

K222056

Device Name
Modular Rotating Hinge Knee System

Indications for Use *(Describe)*

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)

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510(k) Summary

Sponsor	Howmedica Osteonics Corp. dba Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Margaret Klippel Chief Specialist, Regulatory Affairs Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 (201) 831-5559 Email: Margaret.klippel@stryker.com
Date Prepared:	January 4, 2023
Proprietary Name:	Global Modular Replacement System
Common Name:	Hip Replacement, Rotating Hinge Knee Replacement
Regulatory Class:	Class II
Classification Panel:	87, Orthopedic
Regulation:	888.3350, 888.3510, 888.3353, 888.3358
Product Codes:	JDI, KRO, LZO, LPH

Legally Marketed Devices to which Substantial Equivalence is Claimed:

Predicate Howmedica Osteonics (aka Stryker Orthopaedic) Global Modular Replacement System devices were cleared per the following primary 510(k) submission:

Submission Number	Device Name	Product Codes
K023087	Global Modular Replacement System	JDI, KRO

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

Submission Number	Device Name	Product Code(s)
K952970	Modular Replacement System	JDI, KRO
K022403	GMRS Press Fit Stems with HA	LZO
K031217	11mm GMRS Press Fit Stems with HA	LZO
K032581	GMRS Anteverted Proximal Femoral Component	LPH

Submission Number	Device Name	Product Code(s)
K040749	Modular Replacement System Cemented Stems	KRO
K002552	Modular Rotating Hinge Knee	KRO

Reason for 510(k) Submission:

The purpose of this submission is to modify the labeling of the Global Modular Replacement System components to add MR Conditional language. An additional contraindication is being added to the GMRS Press Fit Stems with Hydroxyapatite.

Device Description:

The Global Modular Replacement System 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 or the Modular Rotating Hinge Knee System. 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.

Indications for Use

The Stryker Global Modular Replacement System components 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 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 Global Modular Replacement System Press Fit Stems with HA Coating (presented in K022403, and K031217):

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

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 Modular Replacement System Cemented Stems (cleared in K040749):

- Femoral and/or proximal tibial replacement due to:
    - Trauma
    - Failed previous prosthesis
    - 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.

Summary of Technological Characteristics:

There have been no changes to the technological characteristics of the subject Global Modular Replacement System devices as a result of the revision to the labeling to add MR Conditional language. The subject GMRS components have the same design and are manufactured from the same materials as the corresponding proximal femoral bodies and distal stems of the predicate devices.

Non-Clinical Testing:

The Global Modular Replacement System has been evaluated for use in a Magnetic Resonance Environment through non-clinical testing as outlined in the FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff", dated May 20, 2021. This testing was conducted to characterize the compatibility of Stryker Orthopaedics GMRS passive implants in the MR environment. FDA guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices –Guidance for Industry and FDA Staff", dated March 22, 2016, was also consulted for the heating evaluations performed. Testing was performed according to the standards listed below:

- **Magnetically Induced Displacement Force Test**
  Performed per ASTM F2052-15, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

- **Magnetically Induced Torque Test**
  Performed per ASTM F2213-17, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

- **Image Artifact Test**
  Performed per ASTM F2119-07 (2013), *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

- **Heating by RF Fields Test**
  Performed per ASTM F2182-19e1, *Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging*

Additional analyses have been performed to address heating in the tissue of interest as indicated in the May 2021 guidance document.

The labeling of the GMRS system has been modified to include the MR conditional symbol and to provide the parameters under which a patient who has the device can be safely scanned. The labeling of the GMRS Press Fit Stems with Hydroxyapatite has also been revised to add an additional contraindication.

Clinical Testing:

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

Conclusion:

Based upon a comparison of the intended use, materials, summary of technological characteristics, and preclinical evaluation, the subject Global Modular Replacement System components are considered substantially equivalent to the predicate devices identified in this premarket notification.