



December 8, 2023

Howmedica Osteonics Corp aka Stryker Orthopaedics
Denise Daugert
Principal Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K233261

Trade/Device Name: Global Modular Replacement System
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
Dated: September 28, 2023
Received: September 29, 2023

Dear Denise Daugert:

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

Indications for Use

510(k) Number (if known)
K233261

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)
K233261

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)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K233261

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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Indications for Use

510(k) Number (if known)
K233261

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)

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 aka Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Denise Daugert
Principal Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
(201) 831-5413

Date Prepared: September 28th, 2023

Proprietary Name: Global Modular Replacement System

Common Name: Hip Replacement, Rotating Hinge Knee Replacement

Regulatory Class: Class II

Classification Panel: 87, Orthopedic

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)

Product Codes: JDI, KRO, 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 510(k) submission:

<u>Submission Number</u>	<u>Device Name</u>	<u>Product Codes</u>
K222056	Global Modular Replacement System	JDI, KRO, LPH, LZO

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

<u>Submission Number</u>	<u>Device Name</u>	<u>Product Codes</u>
K023087	Global Modular Replacement System	JDI, KRO
K952970	Modular Replacement System	JDI, KRO
K032581	GMRS Anteverted Proximal Femoral Component	LPH
K040749	Modular Replacement System Cemented Stems	KRO

Reason for 510(k) Submission:

The purpose of this “Changes Being Effected” premarket notification is to modify the labeling to add a contraindication for the Global Modular Replacement System components.

Additionally, MRI 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 May 20, 2021).

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. The subject Global Modular Replacement System components are unchanged since the last premarket notification for the devices in K222056.

Intended 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 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

Summary of Technological Characteristics:

Neither the addition of the contraindication for which this “Changes Being Effected” premarket notification is being submitted, nor the update to the MRI information, will change the technological characteristics of the subject devices.

Non-Clinical or Clinical Testing:

No additional testing was conducted for this submission, as the only changes being made are to modify the labeling to add a contraindication and an update to the MRI safety information to align with an FDA guidance document. Testing performed in the previously cleared premarket notifications is applicable to this submission.

Conclusion:

The subject devices are substantially equivalent to their predicate devices. The subject devices are identical to their respective predicate devices in regards to intended use, indications for use, design, materials, technological characteristics, operational principles, sterility, and packaging materials as described in the last premarket notification for the subject devices. The purpose of this “Changes Being Effected” premarket notification is to modify the labeling to add a contraindication for the Global Modular Replacement System components. Additionally, MRI 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 May 20, 2021).