April 21, 2023

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

Re: K223069
Trade/Device Name: Modular Rotating Hinge Knee System; KRH All Poly Tibial Component; Duracon Knee System Wedges, Stems, Stryker Stems; Total Stabilizer Offset Adapter; GMRS Pediatric Tibial Bearing Component; MRS Pediatric All Poly Tibial Component
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JWH, LGE
Dated: March 22, 2023
Received: March 23, 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,

Jesse Muir -S

Jesse Muir, Ph.D.
Acting 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)*

K223069

Device Name

Modular Rotating Hinge Knee System, KRH All Poly Tibial Component

Indications for Use *(Describe)*

The Modular Rotating Hinge Knee System is intended to be implanted with bone cement for the following conditions:

- 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/or
- Revision is required of a failed prostheses where there has been gross instability, with or without bone loss or inadequate soft tissue

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.

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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)*

K223069

Device Name

Duracon Knee System Wedges, Stems, Stryker Stems

Indications for Use *(Describe)*

Indication for Use for Duracon Components (Cobalt Chrome & Titanium Stems, and Tibial Wedges) and Stryker Stem Components:

Indications for use of total knee replacement prostheses include:
• noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
• rheumatoid arthritis;
• correction of functional deformity;
• revision procedures where other treatments or devices have failed;
• post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and
• irreparable fracture of the knee.

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

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

510(k) Number *(if known)*

K223069

Device Name

Total Stabilizer Offset Adapter

Indications for Use *(Describe)*

Indications for US and Rest of World:
Indications for use of total knee replacement prostheses include:
1) Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
2) Rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed;
5) Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
6) Irreparable fracture of the knee

When the Total Knee Replacement Prosthesis is used with the components of the Modular Rotating Hinge Knee System, the indication for the Modular Rotating Hinge Knee with Offset Adapters is as follows:
The Rotating Hinge Knee Systems are intended to be implanted with bone cement for the following condition(s):
1) There is destruction of the joint surfaces, with or without significant bone deformity.
2) The cruciate and/or collateral ligaments do not stabilize the knee joint.
3) The ligaments are inadequate and/or the musculature is weak and/or,
4) Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

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

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

510(k) Number *(if known)*

K223069

Device Name

GMRS Pediatric Tibial Bearing Component

Indications for Use *(Describe)*

Replacement of the distal femur and/or proximal tibia 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. This smaller size component is intended to be used in patients with a smaller bone structure, or in skeletally immature patients. This component is intended for use with bone cement.

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)*

K223069

Device Name

MRS Pediatric All Poly Tibial Component

Indications for Use *(Describe)*

MRS Pediatric All Polyethylene Tibial Component is intended to be used in oncology patients where radical resection of the distal femur/proximal tibia is required. Additional indications include limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage includes surgical intervention for severe trauma, failed previous knee arthroplasties, 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: April 21, 2023

Proprietary Name: Modular Rotating Hinge Knee System
KRH All Poly Tibial Component
Duracon Knee System Wedges, Stems, Stryker Stems
Total Stabilizer Offset Adapter
GMRS Pediatric Tibial Bearing Component
MRS Pediatric All Poly Tibial Component

Common Name: Rotating Hinge Knee System
Artificial Knee Components

Regulatory Class: Class II

Classification Panel: 87, Orthopedic

Regulation: 888.3510 – Knee joint femorotibial metal/polymer constrained cemented prosthesis
888.3530 – Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
888.3560 – Knee joint patellofemorotibial polymer/metal polymer semi-constained cemented prosthesis

Product Codes: KRO, LGE, JWH

Legally Marketed Devices to which Substantial Equivalence is Claimed:

Predicate Modular Rotating Hinge Knee Systems were cleared per the following primary 510(k) submission:

- Modular Rotating Hinge Knee System - K994207 (product code KRO)

The following are additional legally marketed reference devices used to support substantial equivalence:

Submission Number	Device Name	Product Code(s)
K001548	MRH Crossover Tibial Bearing Component	KRO

Submission Number	Device Name	Product Code(s)
K001957	MRH Tibial Rotating Component	KRO
K002552	Modular Rotating Hinge Knee	KRO
K031480	GMRS Rediatric Tibial Bearing Component	KRO
K060360	MRH Knee with Offset Adapters	KRO
K792089	Kinematic Knee System	JWH
K972863	Duration Stabilized UHMWPE Knee Components	JWH
K915512	Duracon Total Knee Tibial Components	JWH
K973164	Howmedica Total Stabilizer Knee Components	JWH
K924482	Howmedica Total Knee Stem Extenders	JWH
K992346	Kinematic II Rotating Hinge Knee	LGE, KRO
K904208	Kinemax Superstabilizer Knee	JWH

Purpose of the Submission:

The purpose of this submission is to modify the labeling of the Modular Rotating Hinge Knee System and compatible components to add MR Conditional labeling.

Device Description

Modular Rotating Hinge Knee System

The Modular Rotating Hinge (MRH) Knee System is a tri-compartmental knee system that consists of a stemmed femoral component and a stemmed tibial rotation component, connected by a set of bushings and an axle. A bumper locks this assembly. This assembly provides motion through the axle/bushing combinations in the flexion/extension plane. The articulation between the cylindrical bearing surfaces on the underside of the tibial rotating component and a tibial insert provide motion in the rotation plane. The tibial insert is assembled to a tibial stemmed tray which incorporates a longitudinal bore to accept a tibial sleeve.

The Modular Rotating Hinge Knee System is designed to provide varus/valgus stability throughout the range of motion, internal/external rotation about the tibial axis, constrained by the bearing surface radius on the tibial rotating component, and an extensive range of size, modularity and resection options. The implant system consists of a femoral component in five sizes, a tibial rotating component in five sizes, tibial crossover bearing components in various sizes, bumper inserts, tibial and femoral augmentation components and a tibial sleeve. The MRH Knee System is compatible with components of the

Kinemax/Kinematic Knee System, Duracon Knee System, Howmedica Total Stabilizer Knee System, and the GMRS/MRS System.

Intended Use

The Stryker Modular Rotating Hinge Knee System and the compatible components are all sterile, single-use devices. Specific Indications for Use are listed below.

Modular Rotating Hinge Knee Systems and KRH All Poly Tibial Components

Rotating Hinge Knee Systems are intended to be implanted with bone cement for the following condition(s):

1) There is destruction of the joint surfaces, with or without significant bone deformity.
2) The cruciate and/or collateral ligaments do not stabilize the knee joint.
3) The ligaments are inadequate and/or the musculature is weak and/or,
4) Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

Duracon Knee System Wedges, Stems, Stryker Stems

Indications for US and Rest of World:

Indications for use of total knee replacement prostheses include:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
2) rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed;
5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and
6) irreparable fracture of the knee.

Total Stabilizer Offset Adapter

Indications for use of total knee replacement prostheses include:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
2) rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed;
5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and
6) irreparable fracture of the knee.

When the Total Knee Replacement is used with the components of the Modular Rotating Hinge Knee System, the indications for use for the Modular Rotating Hinge Knee with Offset Adapters is as follows: condition(s):

1) There is destruction of the joint surfaces, with or without significant bone deformity.
2) The cruciate and/or collateral ligaments do not stabilize the knee joint.
3) The ligaments are inadequate and/or the musculature is weak and/or,
4) Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

GMRS Pediatric Tibial Bearing Component

Replacement of the distal femur and/or proximal tibia 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. The smaller size component is intended to be used in patients with a smaller bone structure or in skeletally immature patients. This component is intended for use with bone cement.

MRS Pediatric All Poly Tibial Component

MRS Pediatric All Polyethylene Tibial Component is intended to be used in oncology patients where radical resection of the distal femur/proximal tibia is required. Additional indications include limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage includes surgical intervention for severe trauma, failed previous knee arthroplasties, and/or oncology indications.

Summary of Technological Characteristics:

There have been no changes to the technological characteristics of the subject Modular Rotating Hinge Knee System and compatible comonents as a result of the revision to the labeling to add MR Conditional language. The subject Modular Rotating Hinge Knee Systems and compatible comonents have the same designs and are manufactured from the same materials as the corresponding predicate devices.

Non-Clinical Testing:

Non-clinical testing as outlined in the FDA guidance document titled "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Guidance for Industry and Food and Drug Administration Staff," dated March 22, 2016, was conducted 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 Heathing 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 Modular Rotating Hinge Knee Systems and compatible components have 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.

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 Modular Rotating Hinge Knee Systems and compatible components are considered substantially equivalent to their corresponding predicate devices identified in this premarket notification.