March 1, 2022

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

Re: K212187
Trade/Device Name: Restoration® Modular Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, KWL, KWY, KWZ, LWJ, LZO, MAY, MBL, MEH
Dated: February 14, 2022
Received: February 15, 2022

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, 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)*

K212187

Device Name
Restoration® Modular Hip Systems

Indications for Use *(Describe)*

The Restoration® Modular Hip System is indicated for use in:
• Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed; and
• Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indications specific to the Restoration Modular Hip System:
The Restoration® Modular Hip System is intended to be used for primary and revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

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.

510(k) Summary

Sponsor Howmedica Osteonics Corp. dba Stryker Orthopaedics
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Mahwah, NJ 07430

Contact Person Margaret Klippel Chief Specialist, Regulatory Affairs
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325 Corporate Drive
Mahwah, NJ 07430
201-831-5559

Email: Margaret.klippel@stryker.com

Date Prepared: February 28, 2022

Proprietary Name: Restoration® Modular Hip System

Common Name: Total Hip Joint Replacement

Regulatory Class: Class II

Classification Panel: 87, Orthopedic

Regulation: 888.3358

Product Codes: LPH, JDI, KWL, KWY, KWZ, LWJ, LZO, MAY, MBL, MEH

Legally Marketed Devices to which Substantial Equivalence is Claimed:

Predicate Howmedica Osteonics (aka Stryker Orthopaedic) Restoration® Modular Hip Systems were cleared per the following primary 510(k) submission:

Submission Number	Device Name
K051363	Restoration® Modular System

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

Submission Number	Device Name
K193233	Restoration® Modular Hip System
K121308	Hip Systems
K050138	Restoration® Modular System
K040734	Restoration® Modular System

K022549	Restoration® Modular System
K013106	2 Piece Modular Hip Stem
K153345	Stryker Orthopaedics Hip Systems
K171768	Stryker Orthopaedics Trident II Acetabular System

Reason for 510(k) Submission:

The purpose of this submission is to modify the labeling of the Restoration® Modular Hip System proximal femoral bodies and distal stems to add MR Conditional language.

Device Description:

The Restoration Modular Hip System is a modular femoral replacement system. It is comprised of a proximal femoral body, a distal stem, and a locking bolt. The system is assembled utilizing a male/female taper, and a locking bolt to lock the proximal femoral body and distal stem. Many of the components are available in a wide variety of sizes, lengths and geometries to satisfy anatomical requirements and surgeon needs. The implants are fabricated from Titanium alloy (Ti-6Al-4V-ELI);some implants feature a plasma sprayed titanium and plasma sprayed Hydroxyapatite coating. The implants are intended for cementless use.

PROXIMAL FEMORAL BODIES

The proximal femoral bodies are available in three different styles: Cone, Broached, and Calcar, in a range of sizes. Each proximal femoral body features a plasma-sprayed Hydroxyapatite coating over plasma-sprayed Titanium.

DISTAL STEMS

The stems are available in a range of diameters and lengths, straight or curved, to fit various patient anatomical requirements. The distal stems are available in two different styles: Plasma Distal Stems and Conical Distal Stems. The Plasma Distal Stems are fabricated from Titanium alloy (Ti-6Al-4V-ELI) and feature a plasma-sprayed Hydroxyapatite coating over plasma-sprayed Titanium. The Conical Distal Stems are fabricated from Titanium alloy (Ti-6Al-4V-ELI) and are grit blasted, fluted components with a taper extending the length of the stem. The Conical Distal Stems do not have a plasma sprayed Titanium or plasma sprayed Hydroxyapatite coating.

Indications for Use:

The Restoration® Modular Hip System is indicated for use in:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indications specific to the Restoration Modular Hip System:

The Restoration® Modular Hip System is intended to be used for primary and revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

Summary of Technological Characteristics:

There have been no changes to the technological characteristics of the subject Restoration® Modular Hip System devices as a result of the revision to the labeling to add MR Conditional language. The subject Restoration® Modular Hip System proximal femoral bodies and distal stems 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:

Non-clinical testing as outlined in the FDA guidance document titled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff," dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics Restoration Modular Hip System in the MR environment. Stryker also consulted 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, 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*

The labeling of the Restoration® Modular Hip 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.

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 Restoration® Modular Hip System proximal femoral bodies and distal stems are considered substantially equivalent to the corresponding proximal femoral bodies and distal stems of the predicate devices identified in this premarket notification.