December 21, 2021

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

Re: K213129
Trade/Device Name: Restoration Modular 115mm Conical Distal Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, MEH, KWZ, JDI, MAY, MBL
Dated: September 23, 2021
Received: September 27, 2021

Dear Allison Byrne:

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,

for

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)*

K213129

Device Name
Restoration Modular 115mm Conical Distal Stem

Indications for Use *(Describe)*

• 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.
• 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.

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510(k) Summary

Sponsor Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics
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Date Prepared: September 23rd, 2021

Proprietary Name: Restoration Modular 115mm Conical Distal Stem

Common Name: Total Hip Joint Replacement

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR § 888.3353)
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR § 888.3358)
Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR § 888.3310)
Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3350)

Product Codes: LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer
JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish

MBL - prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:

- Restoration Modular Conical Distal Stem (K013106, K022549, K121308)

Reason for 510(k) Submission:

The purpose of this submission is to introduce a line extension to the Restoration® Modular Hip System, specifically a new straight, conical distal stem.

Device Description:

The subject Restoration Modular 115mm Conical Distal Stem is a line extension to the Restoration Modular Hip System. The Restoration Modular Hip System is a modular femoral replacement system comprised of three main components: the Restoration Modular Proximal Femoral Body, the Restoration Modular Distal Stem, and the Locking Bolt. Each of these components feature unique design iterations and are offered in a range of sizes, allowing for independent sizing of the proximal femoral body and the distal stem. The distal stem addresses fixation and stability, and the proximal femoral geometry allows for adjustments to anteversion, height, and offset. The Restoration Modular Hip System is designed to attain fixation and restore hip biomechanics.

The subject device is a sterile, single-use device designed to be press-fit into a prepared femoral canal for either primary or revision total hip arthroplasty and is labeled as MR Conditional. The Restoration Modular 115mm Conical Distal Stem utilizes a male locking taper for mating with one of the compatible Restoration Modular Proximal Femoral Bodies and Locking Bolt.

Intended Use:

The subject Restoration Modular 115mm Conical Distal Stem is a sterile, single-use device intended for use in total hip arthroplasty.

Indications for Use:

- 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.
- 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:

The Restoration Modular Conical Distal Stem is a sterile, single-use device that is intended to be press-fit into a prepared proximal femur for cementless fixation in either primary or revision total hip arthroplasty. The predicate device is the straight Restoration Modular Conical Distal Stem, herein referred to as the predicate Restoration Modular Conical Distal Stem. The predicate

Restoration Modular Conical Distal Stem is currently available in 2 lengths, 155mm or 195mm, each available in 15 diameters ranging from 14mm to 28mm (in increments of 1mm). The subject device introduces an additional straight conical distal stem component into the currently marketed Restoration Modular Hip System. The subject device is herein referred to as the Restoration Modular 115mm Conical Distal Stem and is available in 12 diameters ranging from 12mm to 23mm (in increments of 1mm).

The predicate Restoration Modular Conical Distal Stem and the subject Restoration Modular 115mm Conical Distal Stem are both straight, conical, fluted components with a taper extending the length of the stem, leading to a diametrically larger proximal section and smaller distal section. Both stems are machined from Ti-6Al-4V ELI alloy per ASTM F136 that is shot peened and then grit blasted after machining. They share an identical male locking taper that mates with the currently marketed compatible cone and calcar proximal femoral bodies.

Non-Clinical Performance Data:
The following non-clinical laboratory testing and engineering analyses were conducted to determine substantial equivalence:

- Distal Stem Fatigue Testing per ISO 7206-4:2010/AMD 1:2016
- Biocompatibility evaluated per ISO 10993-1:2018
- Biocompatibility of the device packaging evaluated per ASTM F2475-20
- Shelf-life validated per the following standards:
    - ISO 11607-1:2019
    - ISO 11607-2:2019
    - ASTM F1980-16
    - Testing performed per the following methods:
        - ASTM F1886/F1886M-16
        - ASTM F1929-15
        - ASTM F88/88M-15
        - ASTM F2096-11(2019)
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2019 was used for pyrogenicity testing to achieve an endotoxin limit of < 20EU/Device.

The subject Restoration Modular 115mm Conical Distal Stem has been submitted as MR Conditional. In alignment with FDA guidance document titled "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," dated May 20, 2021, evaluations were performed according to the standards listed below:

- Magnetically Induced Displacement Force performed per ASTM F2052-15
- Magnetically Induced Torque performed per ASTM F2213-17
- Heating by RF Fields performed per ASTM F2182-19
- Image Artifact performed per ASTM F2119-07 (2013)

Clinical Testing:
Clinical testing was not required as a basis to support substantial equivalence.

Conclusion:
Based upon an evaluation of intended use, indications for use, technological characteristics, principles of operation, and non-clinical performance data, the subject Restoration Modular 115mm Conical Distal Stem is substantially equivalent to the predicate Restoration Modular Conical Distal Stem.