August 11, 2022

Stryker
Gregg Ritter
Senior Staff Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K220731
Trade/Device Name: Insignia Hip Stem, 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: MEH, LZO, LWJ, KWZ, KWL, KWY, JDI, LPH, MAY, MBL
Dated: July 13, 2022
Received: July 14, 2022

Dear Gregg Ritter:

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220731

Device Name
Insignia Hip Stem

Indications for Use *(Describe)*
Hip Arthroplasty Indications:

• Painful, disabling joint disease of the hip resulting from: noninflammatory degenerative joint disease (including osteoarthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
• Revision of previous unsuccessful femoral head replacement, hip arthroplasty or other procedure.
• Correction of functional deformity
• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Insignia Hip Stems with compatible Howmedica Osteonics Constrained Liners:

• When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indication specific to use of Insignia Hip Stems with compatible ADM and MDM Acetabular Components:

• When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks

Insignia Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K220731

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 Stryker Orthopaedics
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Mahwah, NJ 07430

Contact Person Gregg Ritter
Senior Staff Specialist, Regulatory Affairs
Stryker Orthopaedics
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Ph: 201-831-5718

Date Prepared: August 11, 2022

Proprietary Name: Insignia Hip Stem, 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)

Product Codes:
MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
LWJ – prosthesis, hip, semi-constrained, metal/polymer, uncemented (Insignia Hip Stem only)
KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer
KWL - prosthesis, hip, hemi-, femoral, metal (Insignia Hip Stem only)
KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (Insignia Hip Stem only)
JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (Restoration Modular 115mm Conical Distal Stem only)
MBL - prosthesis, hip, semi-constrained, uncemented, metal/polymer, Porous (Restoration Modular 115mm Conical Distal Stem only)

Legally Marketed Primary Predicate Device to Which Substantial Equivalence is Claimed:

- Insignia Hip Stem (K211703)

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:

- Accolade II Hip Stem (K153345)
- Trident II Acetabular System (K171768)
- Restoration Modular 115mm Conical Distal Stem (K213129)

Insignia Hip Stem

Device Description:

The Insignia Hip Stem is a sterile, single-use device that is intended for cementless fixation into a prepared femoral canal for either primary or revision total or hemi hip arthroplasty.

The Insignia Hip Stem includes 12 sizes ranging from Size 0 through 11. Each stem size is offered in a Standard Offset and a High Offset option at a single 132 degree neck angle. The stem is designed only for use with compatible V40 Howmedica Osteonics' femoral heads, sleeves and acetabular components.

The Insignia Hip Stem is manufactured from Ti6Al4V ELI alloy and the device features hydroxyapatite coating over a commercially pure titanium plasma sprayed surface for cementless fixation.

Intended Use:

The Insignia Hip Stem is intended for use in primary and revision total and hemi hip arthroplasty to alleviate pain and restore function. The subject hip stem is compatible with V40 heads; ceramic C-taper heads, when used with the V40/C-Taper Adaptor Sleeve; Universal Heads, when used with the V40/Universal Adaptor Sleeve; and Unitrax Heads.

Indications:

There are no changes to the Insignia Hip stem Indications for Use from the original clearance.

Hip Arthroplasty Indications

1. Painful, disabling joint disease of the hip resulting from: noninflammatory degenerative joint disease (including osteoarthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
2. Revision of previous unsuccessful femoral head replacement, hip arthroplasty or other procedure.
3. Correction of functional deformity
4. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Insignia Hip Stems with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indication specific to use of Insignia Hip Stems with compatible ADM and MDM Acetabular Components:

- When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks.

Insignia Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Restoration Modular System

Device Description:

The subject Restoration Modular 115mm Conical Distal Stem is a part of 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:

There are no changes to the Restoration Modular 115mm Conical Distal Stem Indications for Use from the original clearance.

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:
There have been no changes to the technological characteristics of the subject Insignia Hip Stem and Restoration Modular 115mm Conical Distal Stem devices as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:

This premarket notification presents an evaluation to characterize the components of the Insignia Hip Stem System as with respect to magnetically induced displacement force, magnetically induced rotational force, MR-induced image artifacts, and R-F induced heating. The subject Insignia Hip Stem components were evaluated per the following standards:

- Magnetically Induced Displacement Force – 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 – performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- Image Artifact – performed per ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- Heating by RF Fields per ASTM F2182-19, Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging

The labeling 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 in the MR environment.

The subject Restoration Modular 115mm Conical Distal Stem was previously cleared as MR Conditional in cleared 510(k) premarket notification K213129.

Additionally, Insignia Hip Stem and Restoration Modular 115mm Conical Distal Stem have revised contraindications compared to the respective primary predicate devices. The differences in contraindications of the subject devices compared to the predicate devices do not raise any new questions of safety and effectiveness.

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

Conclusion: Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Stryker Orthopaedics Hip Systems are substantially equivalent to the predicate devices identified in this premarket notification.