August 16, 2021

Stryker Orthopaedics
% Gregg Ritter
Senior Staff Specialist, Regulatory Affairs
Howmedica Osteonics Corp aka Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K211703
Trade/Device Name: Insignia Hip 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, KWL, KWZ, KWY, JDI, LPH
Dated: June 2, 2021
Received: June 3, 2021

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

510(k) Number *(if known)*

K211703

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.

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510(k) Summary

Sponsor: Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics
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Mahwah, NJ 07430

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Date Prepared: June 3, 2021

Proprietary Name: Insignia Hip Stem

Common Name: Hip Joint Prosthesis

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (888.3353)
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (888.3360)
Hip joint metal/polymer constrained cemented or uncemented prosthesis (888.3310)
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented (888.3390)
Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (888.3358)

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
KWL - prosthesis, hip, hemi-, femoral, metal

KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer
KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented
JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

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

- Accolade II Hip Stem (K103479, K120578)

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:

- Omnifit HFx (K031744)
- Actis Hip Stem (K202472, K160907, K150862)

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 basic design of the Insignia Hip Stem is similar to other commercially distributed hip stems, such as the Accolade II and Omnifit HFx hip stems. The Insignia Hip Stem is manufactured from Ti-6Al-4V ELI alloy, features a collar, commercially pure titanium plasma sprayed proximal surface, and plasma sprayed hydroxyapatite coating.

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 cemented or uncemented acetabular components.

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.

Indications for Use:

The Insignia Hip stem has similar Indications for Use as the Accolade II Hip Stem.

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.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Insignia Hip Stem is substantially equivalent to the primary predicate Accolade II Hip Stem device in terms of intended use, indications for use, size-specific medial curvature design, materials, performance characteristics and operational principles. The primary predicate Accolade II Hip Stem does not have a collar or HA coating on the distal stem region. The Insignia Hip Stem device is similar in design to the additional predicate Omnifit HFx Hip Stem as both are collared stems. The Insignia Hip Stem is similar to the additional predicate Actis Hip Stem as both have a collar with a hydroxyapatite (HA) coated underside and are both fully HA coated in the distal and proximal stem regions.

Non-Clinical Testing: The following non-clinical laboratory testing was performed, or engineering analysis was conducted to determine substantial equivalence:

- Distal Stem Fatigue Testing per ISO 7206-4
- Neck Fatigue Testing per ISO 7206-6
- Range of Motion Analysis per ISO 21535
- Characterization of the Chemistry, Physical and Mechanical Properties of the coated surfaces:

Test	Method
Calcium to Phosphorus Ratio	ISO 13779-3:2018
Crystallinity and Phase Purity	ISO 13779-3:2018
Preferred Orientation, Crystallite Size and Strain	X-Ray Diffraction
Trace Element Analysis	ISO 13779-3:2018
Solubility Product	ISO 13779-6:2015
Fourier Transform Infrared (FTIR) Spectroscopy	ISO 13779-2:2018 & ISO 13779-6:2015
Dissolution Rate	ASTM F-1926M-14
HA Particle Size Distribution	ISO 13779-6:2015

Titanium Particle Size Distribution	ASTM B214 or ASTM B822
Shear Fatigue Bond Strength	ASTM F-1044-05 & ASTM F-1160-14
Abrasion Resistance	Stryker Internal Method
4 Point Median Fatigue Strength	ASTM F-1160-14
Static Shear Bond Strength	ASTM F-1044-05
Tensile Bond Strength	ASTM F-1147-05
Volume % Voids	ASTM F-1854-15
Void Intercept Length	ASTM F-1854-15

- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an endotoxin limit of < 20EU/Device

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

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