October 21, 2022

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

Re: K222632
Trade/Device Name: UHR Bipolar Implants, Restoration GAP II Implants
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWL, LZO, JDI
Dated: August 24, 2022
Received: August 31, 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.
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)*

K222632

Device Name
UHR Bipolar

Indications for Use *(Describe)*

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Type of Use *(Select one or both, as applicable)*

[x] 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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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)*

K222632

Device Name
Restoration GAP II Acetabular Shell

Indications for Use *(Describe)*

• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post- traumatic arthritis or late stage avascular necrosis.

• Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.

• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

• Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

• Segmental and/or cavitary acetabular defects which make it difficult to restore normal hip biomechanics or to reconstitute the normal structural continuity and integrity of the acetabulum, using standard total hip replacement acetabular components and procedures.

Type of Use *(Select one or both, as applicable)*

[x] 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	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Margaret Klippel Chief Specialist, Regulatory Affairs Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430 Telephone: 201-831-5559
Date Prepared:	October 21, 2022
Proprietary Name:	UHR Bipolar Restoration GAP II Acetabular Shell
Common Name:	Artificial Hip Replacement Components
Regulatory Class:	Class II
Regulation:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353
Product Codes:	KWL – Prosthesis, hip, hemi-, femoral, metal LZO – Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented JDI – Prosthesis, hip, semi-constrained, metal/polymer, cemented

Legally Marketed Device to Which Substantial Equivalence is Claimed:

- UHR Bipolar – K800207
- Restoration GAP II Acetabular Shell – K980774

Additional Predicate Devices

- Stryker Hip Systems Labeling Update – K153345
- Trident II Acetabular System – K171768

Device Description:
The devices covered by this submission are Stryker Hip System components:

- UHR Bipolar femoral head
- Restoration GAP II Acetabular Shell

These devices have been previously determined substantially equivalent in prior 510(k) submissions and are commercially available.

The purpose of this submission is to modify the labeling of these Stryker Hip System components to add MR Conditional labeling.

Indication for Use:
The indications for the subject components are as follows:

UHR Bipolar:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Restoration GAP II Acetabular Shell:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post- traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.
- Segmental and/or cavitary acetabular defects which make it difficult to restore normal hip biomechanics or to reconstitute the normal structural continuity and integrity of the acetabulum, using standard total hip replacement acetabular components and procedures.

Summary of Technological Characteristics:
There have been no changes to the technological characteristics of the subject Stryker Hip System 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:

The following non-clinical laboratory testing was performed to determine substantial equivalence:

- Magnetically Inducted Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment

- Magnetically Induced Torque – performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR 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 near Passive Implants during MR 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.

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

Conclusion: The Stryker Hip System components are substantially equivalent to the predicate devices identified in this premarket notification.