April 22, 2021

Howmedica Osteonics Corp. a.k.a. Stryker Orthopaedics
Alexandra Kirby
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K210893
Trade/Device Name: Restoration Anatomic Shell
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
Dated: March 24, 2021
Received: March 25, 2021

Dear Alexandra Kirby:

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,

Vesa Vuniqi
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)*
K210893

Device Name
Restoration Anatomic Shell

Indications for Use *(Describe)*

• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic 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 is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM Liners
• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
• Dislocation risks

When used with Constrained Liner:
• The Trident Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Restoration Anatomic Shell is indicated for cementless use only.

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

Name and Address of Sponsor and Manufacturing Site	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person:	Alexandra Kirby Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 (201) 831-5963
Alternate Contact:	Paula McCarthy Senior Manager, Regulatory Affairs & Labelling Stryker Orthopaedics Raheen Business Park Limerick Ireland V94 X6T4 +353 (0)87 2824403
Date Prepared:	March 24, 2021
Proprietary Name:	Restoration Anatomic Shell
Common Name:	Total Hip Joint Replacement

Classification Name and Reference: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358)

Product Codes: LPH

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

- Restoration Anatomic Shell (K153345)

Legally Marketed Reference Device Used to Support Substantial Equivalence:

- Restoration Acetabular Wedge Augment (K153345, K102019)
- Restoration Anatomic Shell (K151264, K142462)

Device Description

The Restoration Anatomic Shell is a sterile, single-use device that is intended for cementless fixation into a prepared acetabulum for either primary or revision Total Hip Arthroplasty. The subject device substrate is manufactured from Ti-6Al-4V ELI alloy and has a porous CP-Ti coating. The materials, design features and screw hole locations of the subject Restoration Anatomic Shell are identical to the predicate device cleared via premarket notifications K153345, K151264, and K142462.

Intended Use

There is no change to the intended use for the subject device.

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic 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 is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM Liners

- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks

When used with Constrained Liner:

- The Trident Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Restoration Anatomic Shell is indicated for cementless use only.

Summary of Technological Characteristics

The subject device is identical in intended use, indications for use, product design, product materials, and operational principles as the predicate device. The subject device is different from the predicate device in terms of the packaging configuration. The current packaging configuration features a double layer of packaging; the outer packaging layer is the sterile barrier, and the inner packaging layer is a protective layer. The proposed packaging configuration features an inner packaging layer that is Surlyn sealed to Tyvek lidding which is then placed into an outer sterile barrier layer consisting of pre-form rigid blister tray sealed to Tyvek lidding.

Non-Clinical Testing

There is no change to the device design or device materials. Non-clinical testing was not required as a basis for substantial equivalence.

A ship test study was completed on the subject device to qualify the proposed packaging configuration. Testing was completed per ISO 11607-1, ASTM F1886, ASTM D4169, ASTM F2825, ASTM F88/F88M, ASTM F2096, and ASTM F2097.

Product bioburden and cytotoxicity testing were executed as the proposed packaging configuration constitutes a change in packaging materials that contact the product after final cleaning. Bioburden testing was completed per ISO 11737-1 and cytotoxicity testing was completed per ISO 10993-5.

Clinical Testing

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

Conclusion

The subject Restoration Anatomic Shell is substantially equivalent in intended use, indications for use, product design, product materials, and operational principles to the predicate device. The proposed modifications do not affect safety or effectiveness.