Stryker Orthopaedics
Nora O'connor
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

May 27, 2020

Re: K193233
Trade/Device Name: Restoration® Modular Hip System
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 , JDI, KWL, KWY, KWZ, LWJ, LZO, MAY, MBL, MEH
Dated: April 24, 2020
Received: April 29, 2020

Dear Nora O'Connor:

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 Vesa Vuniqi
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)*
K193233

Device Name
Restoration® Modular Hip System

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.

Additional indications specific to the Restoration Modular Hip System:

The Restoration® Modular Hip System is intended to be used for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Name and Address of Sponsor and Distributor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430 Site Registration Number: 2249697
Name and Address of Manufacturing Site(s)	Stryker Ireland Ltd. Osteonics Tullagreen Building IDA Business & Technology Park Carrigtwohill, Cork, Ireland T45 HE42 Site Registration Number: 9616680
Contact Person:	Nora O'Connor Staff Regulatory Affairs Specialist Stryker Tullagreen Building IDA Business & Technology Park Carrigtwohill, Cork, Ireland T45 HE42

	Phone: 00353-214532529 Email: nora.oconnor@stryker.com
Date Prepared:	May 18, 2020
Proprietary Name:	Restoration® Modular Hip System
Common or Usual Name:	Total Hip Joint Replacement
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR §888.3358 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353 Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR §888.3350 Hip joint metal/polymer constrained cemented or uncemented prosthesis, 21 CFR §888.3310 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR §888.3360 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR §888.3390
Product Codes:	87LPH, 87JDI, 87KWL, 87KWY, 87KWZ, 87LWJ, 87LZO, 87MAY, 87MBL, 87MEH
Regulatory Class:	Class II

Legally Marketed Predicate Device to Which Substantial Equivalence is Claimed:

- Howmedica Osteonics Hip Systems – K121308
- Howmedica Osteonics Restoration Modular System – K022549
- Howmedica Osteonics 2 Piece Modular Hip Stem – K013106

Device Description

The Restoration® Modular Hip System is a bowed shaped femoral distal stem which is plasma-sprayed with commercially pure titanium and coated with PureFix™ hydroxylapatite (HA). The device (6276-5-6XX) is available in stem diameters 11-26 mm and length 317 mm. The design of the device is identical to the bowed plasma distal stem cleared under the predicate device 510(k)s.

A Thermoplastic Polyurethane (TPU) sleeve will be added to the previously cleared packaging configuration and the thickness of the outer carton (cardboard box) will be increased. No changes will be made to the previously cleared sterile barrier materials.

Intended Use

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

Indications for Use:

The Restoration® Modular Hip System is indicated for use in:

- 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.

Additional indications specific to the Restoration Modular Hip System:

The Restoration® Modular Hip System is intended to be used for 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 subject device is identical in intended use, indications for use, product design, product materials, operational principles and sterile barrier materials as the predicate device. The subject device is different from the predicate device in terms of the packaging configuration. A TPU sleeve will be added to the packaging configuration. The thickness of the outer carton will be increased.

Non-Clinical Testing

There have been no changes made 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 introduction of the TPU sleeve to the packaging configuration. A compression test was included as part of the ship test study to qualify the increase in thickness of the outer carton on the subject device. Testing was completed as per ISO 11607-1, ASTM F1886, ASTM F88, ASTM F1929, and ASTM D4169.

Bacterial Endotoxin Testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing on the subject device to meet an endotoxin limit of <20 Endotoxin Units (EU)/device.

Clinical Testing

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

Conclusion

The Restoration® Modular Hip System is substantially equivalent in intended use, indications for use, product design, product materials, operational principles and sterile barrier materials to the predicate device. The proposed modifications do not affect safety or effectiveness.