August 13, 2020

Howmedica Osteonics Corp
Alexandra Kirby
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K193429
Trade/Device Name: Exeter V40 Femoral Stem, Exeter X3 RimFit Cup
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO, JDG, KWY
Dated: July 16, 2020
Received: July 17, 2020

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)*
K193429

Device Name
Exeter® X3® RimFit Cup
Exeter® V40™ Femoral Stem

Indications for Use *(Describe)*
Exeter X3 RimFit Cup

The indications for use for total hip arthroplasty include:
• 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, such as cementless fixation, as indicated by deficiencies of the acetabulum.

The Exeter X3 RimFit Cup is intended for cemented use only.

Exeter V40 Femoral Stem

The indications for use for total and hemi hip arthroplasty include:
• 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,
• treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Exeter V40 Femoral Stem is intended for use in total or hemi hip replacement. It is intended for cemented 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

Sponsor

Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person

Alexandra Kirby
Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5963

Alternate Contact

Krutanjali Shah
Manager, Regulatory Affairs
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5665

Date Prepared: December 9, 2019

Proprietary Name:

Exeter X3 RimFit Cup
Exeter V40 Femoral Stem

Common Name: Total and Hemi Hip Prosthesis

Classification Name:

Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350)
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)

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: JDI, LZO, JDG, KWY

Legally Marketed Device to Which Substantial Equivalence is Claimed:

- Exeter X3 RimFit Cup (K111848)
- Exeter V40 Femoral Stem (K011623, K052718, K110290, K121308, K153345, K173499)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Trident®, Restoration ADM®, and MDM® X3 UHMWPE Acetabular Inserts (K182468)
- Triathlon® X3 UHMWPE Tibial Inserts and Patellar Components (K172634)
- Exeter Centralizer and Exeter 2.5mm Intramedullary Plug (K191414)

Device Description:

The subject Exeter X3 RimFit Cup sterilized by ethylene oxide (EtO) is referred to throughout this submission as the Exeter X3-EtO RimFit Cup. The subject Exeter X3-EtO RimFit Cup is a modified version of the predicate Exeter X3 RimFit Cup and features an alternate terminal sterilization method with EtO, an additional polyethylene resin consolidation method (conventional method which meets the specifications of ASTM F648), an alternate cement spacer material in Acrylic Resin Colacryl® TS2270 PMMA, minor dimensional changes related to flange diameter and blow hole locations, and newly introduced Magnetic Resonance (MR) Conditional labeling. The geometry and design of the subject Exeter X3-EtO RimFit Cup is similar to the predicate Exeter X3 RimFit Cup. There are minor modifications to the flange diameter and blow hole locations between the subject Exeter X3-EtO RimFit Cup and predicate Exeter X3 RimFit Cup. The alternate terminal sterilization method and polyethylene resin consolidation method were previously cleared for Stryker Orthopaedics knee devices in K173849 and Stryker Orthopaedics hip devices in K182468. The alternate cement spacer

material was previously cleared in K191414. The MR Conditional labeling was previously cleared in K171768.

The subject Exeter X3 RimFit Cup sterilized via gas plasma (GP) is referred to throughout this submission as the Exeter X3-GP RimFit Cup and has device designs identical to the predicate Exeter X3 RimFit Cup in terms of design and geometry. In comparison to the predicate Exeter X3 RimFit Cup, the only change to the subject Exeter X3-GP RimFit Cup is that the labeling is updated to add MR Conditional information. The MR Conditional language was previously cleared in K171768.

The subject Exeter V40 Femoral Stem is a modified version of the predicate Exeter V40 Femoral Stem in that the stem component is packaged with two polymethyl methacrylate (PMMA) centralizers that are manufactured from an alternate PMMA material (Acrylic Resin Colacryl® TS2270 PMMA). The alternate PMMA material was previously cleared in K191414. The subject device is identical to the predicate device in terms of design and geometry. The labeling for the subject device maintain the MR Conditional designation that was previously cleared in K171768 and K174399 (certain sizes of Exeter V40 Femoral Stem only).

Indications for Use:

The subject Exeter X3 RimFit Cup and Exeter V40 Femoral Stem devices have the same intended use as their respective predicate devices as specified in the 510(k) submissions for the predicate devices and listed as follows.

Exeter X3 RimFit Cup

The indications for use for total hip arthroplasty include:

- 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, such as cementless fixation, as indicated by deficiencies of the acetabulum.

The Exeter X3 RimFit Cup is intended for cemented use only.

Exeter V40 Femoral Stem

The indications for use for total and hemi hip arthroplasty include:

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

The Exeter V40 Femoral Stem is intended for use in total or hemi hip replacement. It is intended for cemented use only.

Summary of Technological Characteristics:

The subject Exeter X3-EtO RimFit Cup and Exeter V40 Femoral Stem are identical in terms of intended use, indications for use, and principles of operation to their respective predicate devices (Exeter X3 RimFit Cup and Exeter V40 Femoral Stem, respectively). The subject Exeter X3-EtO RimFit Cup and Exeter V40 Femoral Stem are similar in terms of technological characteristics to the predicate devices. There are noted differences between the subject and predicate devices as described in the Device Description header above. The geometry and design of the subject Exeter X3-EtO RimFit Cup is similar to the predicate Exeter X3 RimFit Cup. There are minor modifications to the flange diameter and blow hole locations between the subject Exeter X3-EtO RimFit Cup and predicate Exeter X3 RimFit Cup.

The subject Exeter X3-GP RimFit Cup is identical in terms of intended use, indications for use, and principles of operation to the predicate Exeter X3 RimFit Cup. The predicate Exeter X3

RimFit Cup has been cleared in K111848. The change to add MR Conditional labeling to the existing Exeter X3 RimFit Cup does not impact the technological characteristics. The subject device has the same design and is manufactured from the same materials as the predicate Exeter X3 RimFit Cup.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial eequivalence of the subject devices:

Exeter X3-EtO RimFit Cup

1) Material testing per ASTM F648, ASTM F2565, and FDA Guidance, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" (April 26, 2019).
2) Biocompatibility Evaluation per ISO 10993-1, ISO 10993-7, and FDA Guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' (June 16, 2016)
3) Ethylene oxide sterilization validation per ISO 11135:2014
4) Bacterial endotoxin testing (BET)
5) MRI Analysis per the FDA guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff," dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics total hip passive implants in the MR environment. FDA guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Draft Guidance for Industry and FDA Staff", dated March 22, 2016 was also consulted for the heating evaluations performed.
6) Accelerated Aging Studies of PMMA coupons
7) Effect of Cleaning and Sterilization on the Dimensional Stability of PMMA

Exeter X3-GP RimFit Cup

1) MRI Analysis per the FDA guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff," dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics total hip passive implants in the MR environment. FDA guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Draft Guidance for Industry and FDA Staff", dated March 22, 2016 was also consulted for the heating evaluations performed.

Exeter V40 Femoral Stem

1) Centralizer Insertion
2) Centralizer Retention
3) Winged Centralizer Wing Flexibility
4) Accelerated Aging Studies of PMMA coupons
5) MRI Analysis per the FDA guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff," dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics total hip passive implants in the MR environment. FDA draft guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Draft Guidance for Industry and FDA Staff," dated March 22, 2016 was also consulted for the heating evaluations performed.

Clinical Testing:

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

Conclusion:

The subject Exeter X3 RimFit Cup and Exeter V40 Femoral Stem are substantially equivalent to the respective predicate devices identified in this premarket notification. Device comparison showed that the proposed devices are substantially equivalent in intended use, technological

characteristics, and principles of operation as compared to the respective predicate devices. The proposed modifications do not affect safety and effectiveness.