February 1, 2022

Howmedica Osteonics Corp., dba Stryker Orthopaedics
Lin Song
Senior Manager, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K213701
Trade/Device Name: 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: November 29, 2021
Received: December 1, 2021

Dear Lin Song:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213701

Device Name
Exeter ® X3® RimFit ® Cup

Indications for Use *(Describe)*

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.

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 dba Stryker Orthopaedics
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Date Prepared: January 28, 2022

Proprietary Name: Exeter® X3® RimFit® Cup

Common Name: Total 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 non-Porous uncemented (21 CFR §888.3353)

Hip joint Femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR §888.3360)

Hip joint femora (hemi-hip) metal/polymer cemented or uncemented prothesis (21 CFR §888.3390)

Product Codes: JDI, LZO, JDG, KWY

Legally Marketed Device to Which Substantial Equivalence is Claimed:

- Primary Predicate Device: Exeter V40 Femoral Stem, Exeter X3 RimFit Cup (K193429)
- Secondary Predicate Device: Exeter X3 RimFit Acetabular Cup (K111848)
- Reference Device: Zimmer ZCA All-Poly Acetabular Cups (K191449)

Device Description

This submission covers the subject Exeter X3 RimFit Cups, terminally sterilized by gas plasma (GP) or ethylene oxide (EtO).

The Exeter X3-GP RimFit Cup, terminally sterilized by gas plasma (GP), was previously cleared in K193429 and K111848. It features three subcomponents: a cup manufactured from X3 UHMWPE, a radiopaque wire manufactured from Rex 734 Stainless Steel (Orthinox), and cement spacers manufactured from SG-10 PMMA.

The Exeter X3-EtO RimFit Cup, terminally sterilized by ethylene oxide (EtO), was previously cleared in K193429. It features three subcomponents: a cup manufactured from X3 UHMWPE, a radiopaque wire manufactured from Rex 734 Stainless Steel (Orthinox), and cement spacers manufactured from TS2270 PMMA.

The subject Exeter X3-GP RimFit Cup and Exeter X3-EtO RimFit Cup are compatible for use with Stryker Orthopaedics V40 femoral heads, universal taper femoral heads, and C-Taper femoral heads as previously cleared in K111848.

The purpose of the submission is to modify the labeling to remove a contraindication for obesity.

Indications for Use

There are no changes to the previously cleared indications for use. The indications for use for the subject Exeter X3 RimFit Cups are as follows.

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.

Summary of Technological Characteristics

There have been no changes to the technological characteristics of the subject devices as a result of the revision to the labeling. The subject Exeter X3 RimFit Cups have identical design and are manufactured from the same materials as the predicate Exeter X3 RimFit Cups.

Non-Clinical Testing

Based on the definitions for contraindications and warnings from the FDA Device Labeling Guidance #G91-1, obesity should not be considered a contraindication to total hip arthroplasty, but rather a warning that should be adequately assessed by the surgeon and clearly communicated to the patient. The current subject device labeling already has a warning regarding obesity. Performance testing was not required in support of this labeling modification.

Clinical Testing

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

Conclusion

The subject Exeter X3 RimFit Cups are substantially equivalent to the predicate Exeter X3 RimFit Cups identified in this premarket notification. Device comparison demonstrated that the subject Exeter X3 RimFit Cups devices are identical in design, indications for use, materials, operational principles, and performance characteristics to the predicate Exeter X3 RimFit Cups. The proposed labeling modifications do not affect the safety or effectiveness of the subject devices.