Stryker Orthopaedics
Kirsten Lehmuller
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

March 19, 2018

Re: K173499
Trade/Device Name: Exeter V40 Femoral Stem Hip System, Orthinox V40 Femoral Heads
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: JDG, JDI, KWY, LZO
Dated: February 16, 2018
Received: February 20, 2018

Dear Kirsten Lehmuller:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173499

Device Name
Exeter V40 Femoral Stem Hip System, Orthinox V40 Femoral Heads

Indications for Use *(Describe)*
Exeter® V40™ Femoral Stem Hip System (includes Orthinox V40 Femoral heads)
The Exeter® V40™ Femoral Stem Hip System is intended for use in total or hemi hip replacement. It is intended for cemented use only.

The Exeter® V40™ Femoral Stem Hip System is indicated for:
- 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

**Sponsor** Stryker Orthopaedics
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Mahwah, NJ 07430

**Contact Person** Kirsten Lehmuller
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Mahwah, NJ 07430
201-972-9164

**Date Prepared**: November 9, 2017

**Proprietary Name:** Exeter® V40™ Femoral Stem Hip System

**Common Name**: Artificial Hip Replacement

**Classification Name:** 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 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 V40 Femoral Stems – K011623, K110290, K121308, K153345

Accolade HFx Femoral Stems – K051741, K121308

Biomet Sirius Femoral Hip Stem – K130610, K142295

**Device Description:** The Exeter® V40™ Femoral Stems/Orthinox Femoral Heads are sterile, single-use components intended for cemented total and hemi-hip arthroplasty. The femoral stems have a tapered distal portion with a V40™ neck taper. The stems are available in various offsets and body sizer. The Exeter Hip System continues to be manufactured from the same materials, the same design and the same manufacturing process as the previously cleared Exeter® V40™ femoral stems.

**Intended Use:** The subject devices are intended for use in total or hemi hip arthroplasty. The subject devices are intended for cemented use only.

**Indications:** Exeter® V40™ Femoral Stem Hip System (includes Orthinox V40 Femoral heads)

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

The Exeter® V40™ Femoral Stem Hip System is indicated for:
• 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.

**Summary of Technological Characteristics:** The technological characteristics (material, design, and operational principles) of the Exeter® V40™ Hip System are similar or identical to the predicate devices. The purpose of this submission is to introduce additional stem lengths to the Exeter V40 Hip System that are within the cleared stem lengths range, add additional Orthinox femoral heads, and update compatibility for compatible usage with unipolar and bipolar femoral heads.

**Non-Clinical Testing:** The following non-clinical laboratory testing was performed to determine substantial equivalence:

- Range of Motion Analysis
- Femoral Stem Neck and Body Fatigue, ISO 7206-4 (2010)and ISO 7206-6 (2013)
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 and European Pharmacopoeia Chapter 2.6.14 was used for pyrogenicity testing to achieve an Endotoxin limit of < 20EU/Device and < 20 IU/Device respectively.
- Magnetic Resonance Imaging Analysis: The Exeter Hip System has previously established MRI compatibility in pre-market notification K153345 where worst case combinations were presented. The additional femoral stems do not present a new worst case condition.

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

**Conclusion:** Based upon a comparison of intended use, materials, summary of technological characteristics and performance testing, the Exeter® V40™ Femoral Stem Hip System is substantially equivalent to the predicate devices identified in this premarket notification.