Stryker Orthopaedics
Denise Daugert
Sr. Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

August 28, 2019

Re: K191414
Trade/Device Name: EXETER Centralizer, EXETER 2.5mm Plug
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LZN
Dated: May 24, 2019
Received: May 28, 2019

Dear Denise Daugert:

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,
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)*
K191414

Device Name

EXETER Centralizer and EXETER 2.5mm Intramedullary Plug

Indications for Use (Describe)

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The EXETER Centralizer is intended to be used to centralize the femoral stem within the intramedullary canal and is intended to be used with bone cement.

The EXETER 2.5mm Intramedullary Bone Plug is intended to be used to restrict the migration of bone cement down the femoral canal and permit cement pressurization during total hip arthroplasty and is intended to be used with bone cement.

Type of Use *(Select one or both, as applicable)*

[X] 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 (K191414)

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430 USA
Contact Person	Denise Daugert Sr. Staff Regulatory Affairs Specialist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-5413 Fax: 201-831-4413
Alternate Contact	Krutanjali Shah Manager Regulatory Affairs Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-5665 Fax: 201-831-4465
Date Prepared:	August 28, 2019
Proprietary Name:	EXETER Centralizer and EXETER 2.5mm Intramedullary Plug
Common Name:	Artificial Hip Replacement
Classification Name:	Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3350
Product Codes:	JDI, LZN

Legally Marketed Device to which Substantial Equivalence is Claimed:

EXETER Centralizer - K974054, K011623
EXETER 2.5mm Intramedullary Plug - K980843, K011623, K173499

Device Description: The subject devices, EXETER Centralizer and EXETER 2.5mm Intramedullary Plug, are a modified version of the predicate EXETER Centralizer and EXETER 2.5mm Intramedullary Plug. The subject devices are identical to the predicate devices in design and geometry. The subject centralizers and plugs will be manufactured from Acrylic Resin Colacryl® TS2270, an alternate PMMA material.

The labeling for the modified devices is being updated to add MR Conditional labeling. This labeling was previously cleared in K171768.

Indications For Use:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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Summary of Technological Characteristics:
The subject devices, EXETER Centralizer and EXETER 2.5mm Intramedullary Plug are identical to the predicate devices in intended use, indications, design, and operational principles. The subject devices differ from the predicate devices with regard to material. The subject devices are manufactured from a different PMMA material than the predicate devices.

Non-Clinical Testing:

- Biological Evaluation per ISO 10993-1: 2018 – *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and* FDA Guidance entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'.
- IM Plug Off-Axis Impaction testing
- Centralizer Insertion (fracture) testing; Centralizer retention (pull-out) testing; Centralizer wing flexibility testing
- Material Characterization: Tensile Modulus, Ultimate Tensile Strength, Elongation at Break, Flexural Modulus, Flexural Strength and Izod Impact Strength were performed.
- MRI Analysis

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 Centralizer and EXETER 2.5mm Intramedullary Plug are substantially equivalent to the predicate devices identified in this premarket notification.