Exactech®, Inc.
Zach Sharrah
Senior Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

November 8, 2018

Re: K182462
Trade/Device Name: Exactech® Alteon® Highly Polished Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, KWL, KWZ, KWY
Dated: September 7, 2018
Received: September 10, 2018

Dear Zach Sharrah:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Daniel S. Ramsey -S
2018.11.08 17:31:06 -05'00'

For 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)*
K182462

Device Name
Exactech® Alteon® Highly Polished Femoral Stem

Indications for Use *(Describe)*
All Exactech® Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech® Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

Exactech® Highly Polished Femoral Stems are intended for cemented fixation.

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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Exactech® Alteon® Highly Polished Femoral Stem
Traditional 510(k) – 510(k) Summary

Sponsor:

Exactech®, Inc.
2320 NW 66th Court
Gainesville FL, 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number: 1038671

Date: September 7, 2018

Contact Person:

Zach Sharrah
Sr. Regulatory Affairs Specialist
Telephone: (352) 327-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Alteon® Highly Polished Femoral Stem

Common Name: Femoral Hip Stem

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis (21 CFR 888.3353, Class II, Product Code: LZO)

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360, Class II, Product Code: LWJ)

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360, Class II, Product Code: KWL)

Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310, Class II, Product Code: KWZ)

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390, Class II, Product Code: KWY)

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Avenir Cemented Hip Stem	Zimmer	K131884

Exactech® Alteon® Highly Polished Femoral Stem
Traditional 510(k) – 510(k) Summary

Indication for Use:
All Exactech® Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech® Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

Exactech® Highly Polished Femoral Stems are intended for cemented fixation.

Device Description:
The Exactech® Alteon® Highly Polished Femoral Stem implants are manufactured from forged Cobalt Chromium Alloy (Co-28Cr-6Mo) with a polished neck finish and polished surface finish. The Alteon® Highly Polished Femoral Stems are available in different combinations of stem length, neck offset, and diameter to accommodate an array of patient anatomies. The femoral stem has a 12/14 taper and has a trapezoidal cross-sectional stem geometry with a distal taper.

Alteon® Highly Polished Femoral Stem implants are collarless femoral stems and are intended for cemented use only.

Summary of Technological Characteristics:
The rationale for substantial equivalence of the proposed Exactech® Alteon® Highly Polished Femoral Stems to the predicate and reference devices is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech® Alteon® Highly Polished Femoral Stem and the predicate device have similar Indications for Use statements. Both proposed and predicate device are indicated for osteoarthritis, rheumatic diseases, post-traumatic degenerative problems, and revision of failed previous reconstructions. Both proposed and predicate device are indicated for hemi or total hip arthroplasty.
- **Materials/Surface Finish/Coatings.** Like the predicate device, the proposed Exactech® Alteon® Highly Polished Femoral Stem is a metallic implant with a highly polished surface finish for permanent implantation at the same site of the body.
- **Design Features.** The proposed Exactech® Alteon® Highly Polished Femoral Stem and the predicate device share the same design features; 12/14 taper geometry, neck axis, standard and extended offsets, and offered in a collarless design.
- **Dimensions.** The proposed Exactech® Alteon® Highly Polished Femoral Stem and the predicate device have similar neck offset and stem length dimensions.
- **Sterilization.** The proposed Exactech® Alteon® Highly Polished Femoral Stem and the predicate device are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech® Alteon® Highly Polished Femoral Stem and the predicate device conform to recognized performance standards for total hip replacement devices.

Exactech® Alteon® Highly Polished Femoral Stem
Traditional 510(k) – 510(k) Summary

Non-Clinical Testing:
The following non-clinical testing has been performed to demonstrate that the Exactech® Alteon® Highly Polished Femoral Stems perform as intended and are substantially equivalent to the identified predicate devices:

- Distal Fatigue Testing
- Proximal Fatigue Testing
- Range of Motion Analysis
- Femoral Head Compatibility Testing including; burst testing, fatigue testing, post-fatigue burst testing, and pull-off
- Geometry Comparison of Alteon® HPS to Alteon® HA Femoral Stem

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Exactech® Alteon® Highly Polished Femoral Stems meet recommended limits per FDA's *Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile*.

Substantial Equivalence Conclusion:
Based on consideration of Indications for Use, technological characteristics, and results of non-clinical testing referenced in this submission, it is concluded that the proposed Exactech® Alteon® Highly Polished Femoral Stems are substantially equivalent to the cited cleared predicate devices.