March 10, 2025

Exactech, Inc.
Pedro Ravelo
Regulatory Affairs Specialist
2320 NW 66th Ct.
Gainesville, Florida 32653

Re: K243839
Trade/Device Name: Alteon® HA Femoral Stems
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: MEH
Dated: December 11, 2024
Received: December 13, 2024

Dear Pedro Ravelo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243839

Device Name
Alteon® HA Femoral Stems

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 Alteon HA femoral stems are intended for press-fit 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exactech® Alteon® HA Femoral Stems
Traditional 510(k) – 510(k) Summary

Contact Details

Applicant Name:	Exactech, Inc.
Applicant Address:	2320 NW 66th Ct. Gainesville FL 32653 United States
Applicant Contact Telephone:	352-377-1140
Applicant Contact:	Mr. Pedro Ravelo
Applicant Contact Email:	pedro.ravelo@exac.com
Date Prepared:	07 March 2025

Device Name

Device Trade Name:	Alteon® HA Femoral Stems
Common Name:	Femoral Stem
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number:	888.3353
Product Code(s):	MEH

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162732	Exactech® Alteon® HA Femoral Stems	MEH

Device Description Summary

The proposed Exactech Alteon HA Femoral Stems are intended for press-fit hip arthroplasty.

The Exactech Alteon HA Femoral Stems are manufactured from Ti-6Al-4V ELI (per ASTM F136, ASTM F620) with a grit blast surface and HA coating (per ISO 13779-2). The stem has a 12/14 taper. The Alteon HA Femoral Stems are available in various lengths with standard and extended neck offset configurations, and collared and collarless configurations. The stem has a trapezoidal cross-sectional stem geometry with a distal taper, and it contains vertical and horizontal grooves along its bone contacting surfaces.

The Alteon HA Femoral Stems are compatible with the same femoral components as the predicate:

- Exactech Cobalt Chromium Alloy Femoral Heads (K041906, K121392)
- Exactech Ziramic Zirconia Femoral Heads (K050398, K060107)
- Exactech BIOLOX forte Alumina Femoral Heads (K032964, K051682)
- Exactech BioloxDelta and DeltaOption Femoral Heads and Adapters (K103012,K121392)
- AcuMatch L-series Unipolar endoprostheses (K010081)

- AcuMatch L-Series Bipolar Endoprostheses (K013211)

The Alteon HA Femoral Stems are compatible with the same acetabular components as the predicate:

- AcuMatch A-Series Acetabular Shells and Liners (K993082, K042906)
- AcuMatch A-Series Acetabular GXL Liners (K051556)
- AcuMatch A-Series Acetabular Cups, All-polyethylene, Cemented (K963313)
- Novation Crown Cup Acetabular Shells and Liners (K070479, K100269, K121392, K141960)
- Novation Crown Cup Acetabular Shells with InteGrip (K102975)
- Novation Crown Cup Constrained Liners and Rings (K071676)
- Exactech Integrip Acetabular Shells (K122798)
- Exactech Novation and AcuMatch E-HXL Acetabular Liners (K173583)
- Exactech Alteon Acetabular Cup System (K182502)

Intended Use/Indications 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 Alteon HA femoral stems are intended for press-fit fixation.

Indications for Use Comparison

The subject device and the predicate device have the same indications for use.

Technological Comparison

The subject device and the predicate have the same intended use and basic fundamental scientific technology. The rationale for substantial equivalence between the subject device and the predicate device is based on consideration of the following:

- The subject and predicate devices have the same indications for use.
- The subject and predicate devices are composed of the same or similar biocompatible materials.
- The subject and predicate devices have the same design features.
- The subject and predicate devices have the same dimensions.
- The subject and predicate devices are provided sterile for single use only
- The subject and predicate devices conform to the same recognized performance standards.

Exactech® Alteon® HA Femoral Stems
Traditional 510(k) – 510(k) Summary

The only difference between the subject device and the predicate device is the hydroxyapatite (HA) coating material/process applied to the stem.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following non-clinical testing and engineering analyses were conducted to demonstrate the proposed Alteon HA Femoral Stems perform as intended and are substantially equivalent to the identified predicate devices:

- Engineering analysis of Range of Motion (ROM) per ISO 21535:2007
- Engineering analysis of Stem Neck Fatigue Testing per ASTM F2068-2015 and ISO 7206-6:2013
- Engineering analysis of Distal Stem Fatigue Testing per ASTM F2068-2015 and ISO 7206-4:2010
- HA coating characterization per ISO 13779-2 and FDA Guidance document, 510(k) Information Needed for Hydroxyapatite Coated Orthopaedic Implants, dated February 1997
- Bacterial endotoxins per USP <161>, USP <85> and ANSI/AAMI ST72

There is no clinical testing being submitted as part of this submission.

The difference in the applied HA coating does not change the intended use, safety, or performance requirements of the proposed devices, nor does it adversely affect their safety or effectiveness. This conclusion is based on consideration of nonclinical testing and analysis, including range of motion, fatigue, coating characterization, and biocompatibility assessments completed to establish substantial equivalence of the proposed devices to the predicate devices.