May 19, 2023

Exactech, Inc
Valdimir Talley III
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K221323
Trade/Device Name: Exactech® Alteon® Short Tapered Wedge
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, MEH, JDI, KWY, KWZ, LPH, LWJ
Dated: April 21, 2023
Received: April 24, 2023

Dear Valdimir Talley III:

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 -S

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K221323

Device Name
Exactech® Alteon® Short Tapered Wedge

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.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

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® Short Tapered Wedge Femoral Stems
# Traditional 510(k) – 510(k) Summary

**Sponsor:** Exactech®, Inc
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 327-4824
Fax: (352) 378-2617

FDA Establishment Number 1038671

**Contact Person:** Valdimir Talley III
Regulatory Affairs Specialist

**Date:** August 26, 2022

**Proprietary Name:** Exactech® Alteon® Short Tapered Wedge
**Common Name:** Femoral Stem Hip Prosthesis

**Regulation Number and Classification Names:**
21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis.
21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
21 CFR 888.3310 – Hip joint metal/polymer constrained cemented or uncemented prosthesis.
21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

**Device Class:** Class II

**Product Code:** LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented

**Subsequent Product Codes:**
MEH – Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate
JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
KWY – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented

**Exactech® Alteon® Short Tapered Wedge Femoral Stems**
**Traditional 510(k) – 510(k) Summary**

KWZ – Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer
LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
LWJ – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented

**Classification Panel:** Orthopedic

**Legally Marketed Devices to Which Substantial Equivalence Is Claimed:**

**Table 1: Predicate Device System**

| 510(k) Number | Trade or Proprietary Model Name | Manufacturer |
|---|---|---|
| K140674 | Alteon Tapered Wedge Femoral Stems | Exactech, Inc |

**Table 2: Reference Device**

| 510(k) Number | Trade or Proprietary Model Name | Manufacturer |
|---|---|---|
| K110400 | Taperloc Complete Microplasty Hip System | Biomet Manufacturing Corp. |

**Device Description**
The Exactech Alteon Short Tapered Wedge is a collarless, press-fit femoral stem component to be used in total or hemi hip arthroplasty, and is designed to emphasize medial/lateral fixation of the device and axial/rotational stability when implanted in the femoral/medullary canal.

The Alteon Short Tapered Wedge has seventeen size offerings and two lateral offsets per size. It is made from titanium alloy and includes a 12/14 trunnion, a polished neck region, a commercially pure titanium plasma spray coated press-fit region, and a bead-blasted (satin) distal surface finish. The 12/14 trunnion allows for compatible connection with Exactech femoral heads. As a line extension to the predicate, the proposed Alteon Short Tapered Wedge differs from the predicate in that it features a shortened distal stem length.

**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

**Exactech® Alteon® Short Tapered Wedge Femoral Stems**
**Traditional 510(k) – 510(k) Summary**

failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

## Summary of Device Characteristics Comparison

The rationale for substantial equivalence is based on consideration of the following device use, design characteristics and performance requirements:

- **Indications for Use**
  The subject and the predicate devices have the same indications for use.

- **Materials**
  The subject and the predicate devices are composed of the same materials.

- **Performance Requirements**
  The subject and the predicate devices conform to the same recognized performance standards for total hip replacement devices.

- **Manufacturing and Sterilization**
  The proposed and predicate devices are made using similar manufacturing processes and are provided sterile via gamma radiation for single use only.

- **Design Features**
  The subject and the predicate devices have similar design features.

## Non-Clinical Testing

The following non-clinical testing and engineering analyses were performed to demonstrate that the Exactech Alteon Short Tapered Wedge perform as intended and are substantially equivalent to the identified predicate devices:

- Distally Fixed Fatigue testing (ISO 7206-4 and ASTM F2068)
- Femoral Neck Proximal Fatigue testing (ISO 7206-6 and ASTM F2068)
- Femoral Head Modular junction burst testing, fatigue testing, and pull-off (ISO 7206-10 and ASTM F2009)
- Coating characterization (ASTM F1854)
- Range of Motion analysis (ISO 21535)
- Template Studies
- Cadaveric Evaluation (BS EN 62366-1:2015+A1:2020)

**Exactech® Alteon® Short Tapered Wedge Femoral Stems**
**Traditional 510(k) – 510(k) Summary**

## Substantial Equivalence Conclusion

Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Exactech Alteon Tapered Wedge femoral stems demonstrate substantial equivalence to the referenced predicate devices.