Exactech, Inc.
Liz Howell
Regulatory Specialist
2320 NW 66th Court
Gainesville, Florida 32653

October 22, 2019

Re: K190890
Trade/Device Name: Exactech Alteon Modular Dual Mobility (MDM) System
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
Dated: September 17, 2019
Received: September 19, 2019

Dear Liz Howell:

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,

FOR 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)*

K190890

Device Name
Exactech® Alteon® Modular Dual Mobility (MDM) System

Indications for Use *(Describe)*

The Exactech Alteon Modular Dual Mobility (MDM) System is a component of the Alteon Acetabular System. The Alteon MDM System is indicated for skeletally mature individuals undergoing surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis or post-traumatic degenerative problems of the hip. The Alteon Modular Dual Mobility System is also potentially indicated for ankylosing spondylitis, congenital hip dysplasia and to restore mobility resulting from previous fusion. The Alteon MDM System is also indicated for use in primary or revision patients at a high risk of hip dislocation.

The Alteon Acetabular System is 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.

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Exactech® Alteon® Modular Dual Mobility (MDM) System
Traditional 510(k) - 510(k) Summary

Company:	Exactech®, Inc 2320 NW 66th Court Gainesville, FL 32653
Date:	September 17, 2019
Contact Person:	Liz Howell Regulatory Affairs Specialist Phone: (352) 377-1140 Fax: (352) 378-2617
Proprietary Name:	Exactech® Alteon® Modular Dual Mobility (MDM) System
Common Name:	Total Hip Prosthesis Acetabular Component
Classification Name:	21 CFR 888.3353, Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis Class II
Product Code:	LZO

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Corin Trinity™ Dual Mobility System (K170359)

Reference Devices

- Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners (K173583)
- Exactech® Alteon® Acetabular Cups and Acetabular Liners (K182502)
- Stryker Modular Dual Mobility (MDM™) Liner and X3® Acetabular Insert (K103233)
- Biomet G7 Dual Mobility System (K150522), E1™ Avantage™ Head (a.k.a. E1™ Active Articulation) (K101336)

Device Description

The Alteon® MDM System provides modular implants for use in total hip arthroplasty (THA) to restore patient joint function. The Exactech® Alteon® Modular Dual Mobility (MDM) System is intended for use in total hip replacement as an interface between the acetabulum and femoral heads. The Alteon® MDM liners and inserts are manufactured from CoCr alloy and Ultra-High Molecular Weight Polyethylene containing vitamin E (alpha tocopherol), respectively. The Alteon® MDM liners and inserts are each available in seven configurations. The Alteon® MDM insert inner diameter (femoral head compatibility) includes 22mm or 28mm, while the Alteon® MDM liners are compatible with acetabular shells with outer diameters 46-68mm.

Exactech® Alteon® Modular Dual Mobility (MDM) System
Traditional 510(k) - 510(k) Summary

Indications for Use

The Exactech® Alteon® Modular Dual Mobility (MDM) System is a component of the Alteon® Acetabular System. The Alteon® MDM System is indicated for skeletally mature individuals undergoing surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis or post-traumatic degenerative problems of the hip. The Alteon® Modular Dual Mobility System is also potentially indicated for ankylosing spondylitis, congenital hip dysplasia and to restore mobility resulting from previous fusion. The Alteon® MDM System is also indicated for use in primary or revision patients at a high risk of hip dislocation.

The Alteon® Acetabular System is intended for press-fit fixation.

Summary of Technological Characteristics

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

- **Indications for Use.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices have the same or similar indications for use.
- **Materials.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices are composed of the same or similar biocompatible materials.
- **Design Features.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices have the same or similar design features.
- **Dimensions.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices are dimensionally equivalent or comparable.
- **Sterilization.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech® Alteon® Modular Dual Mobility System components and the predicate devices conform to recognized performance standards for total hip replacement devices.

Non-Clinical Testing

The following biocompatibility testing/analysis, wear analyses, mechanical testing, and engineering evaluations were performed to demonstrate that the Alteon® MDM System performs as intended and is substantially equivalent to the identified predicate devices:

- Biocompatibility Analysis
- Wear Testing
- Fretting/Corrosion Testing
- Impingement Testing
- Lever-Out Testing
- Axial Push-Out Testing
- Torque Out Testing
- Offset Pull-Out Testing
- Range of Motion Analysis

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Alteon® MDM System meets 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, biocompatibility of the proposed devices, and results of wear analyses, mechanical testing, and engineering evaluations, the Exactech® Alteon® Modular Dual Mobility System demonstrates substantial equivalence to referenced predicate devices.