Exactech, Inc
Patrick Hughes
Regulatory Affairs Manager
2320 NW 66th CT
Gainesville, Florida 32653

March 13, 2019

Re: K182502
Trade/Device Name: Exactech® Alteon® Acetabular Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, OQI
Dated: February 14, 2019
Received: February 15, 2019

Dear Patrick Hughes:

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
2019.03.13 15:50:59 -04'00'

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)*
K182502

Device Name
Exactech® Alteon® Acetabular Cup System

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.

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

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Exactech® Alteon® Acetabular Cup System
Traditional 510(k) K182502
510(k) Summary of Safety and Effectiveness

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

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

FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Manager

Date: March 13, 2019

510(k) submission Number: K182502

Trade or Proprietary or Model Name(s): Exactech®
Alteon® Acetabular Cup System

Common Name:
Total Hip Prosthesis Acetabular Component

Classification Name:
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented

Product Code:
LPH, JDI, OQI

Classification Panel:
Orthopedic

Regulation Number
888.3358

Device Class
II

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K993082	Exactech AcuMatch® A-Series	Exactech, Inc
K070479	Exactech Novation® Crown Cup	Exactech, Inc
K100269	Exactech Novation® Crown Cup Line Extensions	Exactech, Inc
K173583	Exactech E-HXL AcuMatch and Novation Acetabular Liners	Exactech, Inc

Exactech® Alteon® Acetabular Cup System
Traditional 510(k) K182502
510(k) Summary of Safety and Effectiveness

Indications for Use:
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Device Description:
Proposed Exactech Alteon Acetabular Cup System implants are acetabular components intended for use as part of total hip arthroplasty. Alteon Acetabular Cup System implants share key design features, materials, Indications for Use statements, geometry, and compatibility with other Exactech acetabular components marketed under the brand names AcuMatch and Novation.

The Alteon Acetabular Cup System includes metallic acetabular cups that feature an Asymmatrix™ porous coating, intended to make the devices compatible with press-fit total hip arthroplasty. Like predicate AcuMatch and Novation liners, Alteon XLE liners are manufactured from Type 1 ultra-high molecular weight polyethylene (UHMWPE) blended with vitamin E. Both cups and liners are available in a range of sizes and geometries intended to give surgeons options for meeting the needs of a range of patient anatomies.

The proposed devices operate using the same fundamental scientific technology, have the same intended use and design features, employ the same materials of construction, are offered in the same product size scopes, and are implanted using a similar surgical technique and the same or similar instrumentation. The only modifications proposed by this submission are dimensional.

Testing Description:
This submission references mechanical testing results and engineering analyses for:

- Wear
- Impingement
- Offset pull-out disengagement per ASTM F1820-13
- Axial disassembly per ASTM F1820-13
- Torque-out disassembly per ASTM F1820-13
- Range of motion

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

Exactech® Alteon® Acetabular Cup System
Traditional 510(k) K182502
510(k) Summary of Safety and Effectiveness

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate proposed Alteon Acetabular Cup System devices are substantially equivalent to cited cleared predicate AcuMatch and Novation acetabular cups and liners.