DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 26, 2017

Exactech, Inc.
Thomas McNamara, RAC
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K162732
Trade/Device Name: Exactech® Alteon® HA 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: MEH
Dated: February 27, 2017
Received: March 1, 2017

Dear Mr. McNamara:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162732

Device Name
Exactech® Alteon® HA 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 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.

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Exactech® Alteon® HA Femoral Stems
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: April 25, 2017

Contact Person: Thomas McNamara, RAC
Regulatory Affairs Specialist
Telephone: (352) 327-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Alteon® HA Femoral Stems

Common Name: Femoral Stem

Classification Name:
Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis, 21 CFR 888.3353, Class II, Product Code MEH

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Exactech Novation Element Press-Fit Femoral Stem	Exactech, Inc	K153649

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 Alteon HA femoral stems are intended for press-fit fixation.

Device Description
The Exactech Alteon HA Femoral Stems are manufactured from Ti-6Al-4V with a polished neck region, grit blast surface and HA coating on the stem body. The stem has a 12/14 taper. The Alteon HA Femoral Stems 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 intended for press-fit applications and are not intended for use with bone cement.

Testing:
An engineering analysis was conducted to evaluate the mechanical properties of the proposed Alteon HA Femoral Stems, including:

- Distal Fatigue Testing
- Proximal Fatigue Testing
- Range of Motion Analysis

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to 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:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Exactech Alteon HA Femoral Stems are substantially equivalent to the cleared Exactech Novation Element Press-Fit Femoral Stem.