DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 31, 2016

Exactech® Incorporated
Thomas McNamara
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K153649
Trade/Device Name: Exactech® Novation® Element Press-fit 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: July 29, 2016
Received: August 1, 2016

Dear Thomas 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 yours,

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)*
K153649

Device Name
Exactech® Novation® Element Press-Fit 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.

- Novation Element press-fit femoral stems with HA coating 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.

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Exactech® Novation® Element Press-Fit Femoral Stem
Traditional 510(k) – 510(k) Summary

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: August 30, 2016

Contact Person: Thomas McNamara
Regulatory Affairs Specialist

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

Proprietary Name: Exactech® Novation® Element Press-Fit Femoral Stem

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:

- Exactech Novation Element Press-Fit Femoral Stem (K080980)

Device Description

The Novation Element Press-Fit Femoral Stem is manufactured from Ti-6Al-4V with a grit blast surface and HA coating. The stem has a 12/14 taper. The Novation Element Press-Fit Femoral stem is available in a standard and high 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 Novation Element Press-Fit Femoral Stems are intended for press-fit applications and are not intended for use with bone cement.

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.

- Novation Element press-fit femoral stems with HA coating are intended for press-fit fixation.

Exactech® Novation® Element Press-Fit Femoral Stem
Traditional 510(k) – 510(k) Summary

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 Novation Element Press-Fit Femoral Stems and the predicate devices have the same indications for use.
- **Materials/Surface Finish/Coatings.** The proposed Exactech Novation Element Press-Fit Femoral Stems and the predicate devices are composed of the same biocompatible substrate materials, and the same or similar surface finish/coatings for permanent implants.
- **Design Features.** The proposed Exactech Novation Element Press-Fit Femoral Stems and the predicate devices share the same design features.
- **Dimensions.** The proposed Exactech Novation Element Press-Fit Femoral Stems and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Exactech Novation Element Press-Fit Femoral Stems and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Novation Element Press-Fit Femoral Stems and the predicate devices conform to recognized performance standards for total shoulder replacement devices.

Non-Clinical Testing
The only modification to the proposed Exactech Novation Element Press-Fit Femoral Stems is the vendor applying the HA coating. No other changes were made to the proposed device. HA coating characterization, distal fatigue testing, and range of motion analysis were performed to demonstrate that the proposed Exactech Novation Element Press-Fit Femoral Stems are substantially equivalent to the identified predicate devices.

Substantial Equivalence Conclusion
Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Exactech Novation Element Press-Fit Femoral Stems demonstrates substantial equivalence to the referenced predicate devices.