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

April 9, 2015

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

Re: K143659
Trade/Device Name: Exactech® Equinoxe® Mega Prosthesis
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Class: Class II
Product Code: KWT, KWS, PHX, HSD
Dated: January 8, 2015
Received: January 12, 2015

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" (21CFR 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)*
K143659

Device Name
Exactech® Equinoxe® Mega Prosthesis

Indications for Use *(Describe)*
The Equinoxe Mega Prosthesis System is intended for use in hemi or total shoulder arthroplasty where proximal humeral resection is deemed necessary in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Correction of functional deformity
- Treatment of acute or chronic fracture with humeral head involvement, which are unmanageable using other treatment
- Traumatic arthritis
- Oncology applications including bone loss due to tumor resection.
- Significant humeral resection which are unmanageable using other treatment methods

The Equinoxe Mega Prosthesis System can be used in either primary or revision arthroplasty procedures.

The Equinoxe Mega Prosthesis System is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in which significant resection of the proximal humerus is necessary, the rotator cuff is irreparable and grossly deficient, and a functional deltoid muscle is present.

The Equinoxe Mega Prosthesis System is not indicated for use with the Equinoxe Reverse Shoulder System components in oncology applications.

The Equinoxe Mega Prosthesis Distal Stems are for cemented use only, while the HA coated Equinoxe Mega Prosthesis Distal Fixation Rings are only for uncemented, press-fit use.

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® Equinoxe® Mega Prosthesis
Traditional 510(k) – 510(k) Summary

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

Date: April 8, 2015

Contact Person: Thomas McNamara
Regulatory Affairs Specialist

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

Proprietary Name: Exactech® Equinoxe® Mega Prosthesis

Common Name: Humeral Stem

Classification Name: Prosthesis, Shoulder, Non-Constrained, Meta/Polymer Cemented, (21 CFR Section 888.3650, Class II, Product Code KWT), Prosthesis, Shoulder, Semi-Constrained cemented prosthesis (21 CFR Section 888.3660, Class II Product Code KWS), Shoulder Prosthesis, Reverse Configuration (21 CFR Section 888.3660, Class II Product Code PHX) Prosthesis, Shoulder, Hemi-, Humeral Metallic Uncemented, (21 CFR Section 888.3690, Class II, Product Code HSD)

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Biomet Comprehensive Segmental Revision System (K111746)

Device Description

The Equinoxe Mega Prosthesis differs from conventional Total Shoulder Arthroplasty implants in that it is intended to replace both the articulating surface (humeral head) as well as the resected humerus. The modular design allows for the surgeon to construct the middle and proximal segments of the prosthesis in various lengths in order to match the length of resected bone, and to maintain the patient's natural arm length.

The prosthesis is manufactured from Ti-6Al-4V and has both Titanium Plasma Spray and HA coated regions. The proximal bodies are available in four sizes (Small, Medium, Large, Extra-Large) and two lengths (+0mm, +12.5mm). The middle segments are available in 3 lengths (25mm, 50mm, 75mm) with one diameter (20mm). The distal stems are available in 3 lengths (80mm, 120mm, 200mm) and 6 diameters (6mm, 7mm, 8mm, 9mm, 11mm, 13mm). The distal fixation rings are available in 17 diameters (17.5mm-33.5mm, 1mm increments). The distal fixation rings are intended for press-fit fixation. The proximal bodies and middle segments have suture through holes to facilitate soft tissue attachment.

Exactech® Equinoxe® Mega Prosthesis
Traditional 510(k) – 510(k) Summary

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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 Equinoxe Mega Prosthesis and the predicate device have similar indications for use. The proposed Exactech Equinoxe Mega Prosthesis is also indicated for use in hemi-shoulder arthroplasty and reverse shoulder arthoplasty. In cases with significant proximal humeral resections, joint stability is the primary concern. The stability of the joint is comparable for hemi and total shoulder indications, because stability is achieved by dynamic muscle balancing. The stability of the joint in a reverse shoulder is achieved via the inverted articular concavities without any requirement for dynamic stability provided by the rotator cuff. The additions of the proposed hemi

and reverse shoulder arthroplasty indications do not create a new intended use for the proposed device.

- **Materials/Surface Finish/Coatings.** The proposed Exactech Equinoxe Mega Prosthesis and the predicate device are composed of similar, biocompatible substrate materials, and the same or similar surface finish/coatings for permanent implants.
- **Design Features.** The proposed Exactech Equinoxe Mega Prosthesis and the predicate device share similar design features. Design differences between the cited predicate device and the propose Exactech Equinoxe Mega Prosthesis include the use of a distal fixation ring and different sizes of distal stems and proximal bodies, as well as the hemi- and reverse shoulder indications.
- **Dimensions.** The proposed Exactech Equinoxe Mega Prosthesis and the predicate device are dimensionally comparable.
- **Sterilization.** The proposed Exactech Equinoxe Mega Prosthesis and the predicate device are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Equinoxe Mega Prosthesis and the predicate device conform to recognized performance standards for shoulder replacement devices.

Non-Clinical Testing
The following clinical literature review, template studies, mechanical testing, and cadaveric evaluation were performed to demonstrate that the Exactech Mega Prosthesis performs as intended and is substantially equivalent to the identified predicate device:

- Clinical Literature Review
- Cadaveric Study
- Plasma Spray Coating Characterization
- Fatigue Testing
- Torsion Testing
- Taper Analysis
- Axial Pull-Off Testing
- Suture Abrasion Testing

Bench testing was conducted to address the design differences between the proposed Exactech Equinoxe Mega Prosthesis and the identified predicate device, including the use of a distal fixation ring and different sizes of distal stems and proximal bodies, as well as the addition of the indication for reverse shoulder arthroplasty.

Substantial Equivalence Conclusion
Based on consideration of indications for use, technological characteristics, and results of combined mechanical testing, cadaveric validation study, and clinical literature review described above, it was concluded that Exactech Equinoxe Mega Prosthesis demonstrates substantial equivalence to the referenced predicate device.