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

February 1, 2017

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

Re: K162726
Trade/Device Name: Exactech® Equinoxe® Preserve Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD, KWT
Dated: December 22, 2016
Received: December 27, 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,

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)*
K162726

Device Name
Exactech® Equinoxe® Preserve Stem

Indications for Use *(Describe)*
The Equinoxe Preserve Stems are indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total arthroplasty, anatomic hemi-arthroplasty, or reverse total arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total arthroplasty and anatomic hemi-arthroplasty are as follows:
- Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head.
- Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Preserve Stems are additionally indicated for use in reverse total arthroplasty in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff or a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Equinoxe Preserve Stems are intended for press-fit applications but may be used with bone cement at the discretion of the surgeon.

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® Preserve Stem
Traditional 510(k) – 510(k) Summary

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

Date: January 26, 2017

Contact Person: Thomas McNamara, RAC
Regulatory Affairs Specialist

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

Proprietary Name: Exactech® Equinoxe® Preserve Stem

Common Name: Humeral Stem

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

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Biomet Comprehensive Primary Shoulder Micro Stem (K060692)
- Exactech Equinoxe Press-Fit Primary Humeral Stem (K042021)
- Biomet Comprehensive Reverse Shoulder (K080642)

Device Description

The Exactech Equinoxe Preserve Stem is a line extension to the range of humeral stems marketed by Exactech under the Equinoxe brand name. The subject device is intended to provide surgeons with a short-stem, distal bone preserving option that is compatible with minimally invasive surgical techniques. The proposed device is manufactured from Ti-6Al-4V and has Titanium Plasma Spray, grit blasted, and polished regions. The stems are available in 10 sizes, with distal stem diameters between 6mm and 15mm, and length of 70mm.

Indications for Use

The Equinoxe Preserve Stems are indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total arthroplasty, anatomic hemi-arthroplasty, or reverse total arthroplasty is determined by the surgeon to be the preferred method of treatment.

Exactech® Equinoxe® Preserve Stem
Traditional 510(k) – 510(k) Summary

Clinical indications for anatomic total arthroplasty and anatomic hemi-arthroplasty, are as follows:

- Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head.
- Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
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The Equinoxe Preserve Stems are intended for press-fit applications but may be used with bone cement at the discretion of the surgeon.

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 Equinoxe Preserve Stems and the predicate devices have similar indications for use.
- **Materials/Surface Finish/Coatings.** The proposed Equinoxe Preserve 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 Equinoxe Preserve Stems and the predicate devices share the same design features.
- **Dimensions.** The proposed Equinoxe Preserve Stems and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Equinoxe Preserve Stems and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Equinoxe Preserve Stems and the predicate devices conform to recognized performance standards for total shoulder replacement devices.

Exactech® Equinoxe® Preserve Stem
Traditional 510(k) – 510(k) Summary

Non-Clinical Testing
The following engineering analyses were performed to demonstrate that the Equinoxe Preserve Stems perform as intended and are substantially equivalent to the identified predicate devices:

- Fatigue Testing
- Subsidence and Pull-out Testing

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
Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Equinoxe Preserve Stems demonstrates substantial equivalence to the referenced predicate devices.