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

March 6, 2017

Exactech Inc
Zach Sharrah
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K162325
Trade/Device Name: Exactech Equinoxe Reverse Shoulder Locking Cap, Exactech Equinoxe Reverse Shoulder Compression Screws, Exactech Equinoxe Reverse Shoulder Glenosphere Locking Screw
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS
Dated: February 13, 2017
Received: February 14, 2017

Dear Zach Sharrah:

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)*
K162325

Device Name
Exactech® Equinoxe® Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap

Indications for Use *(Describe)*
The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

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® Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap**
**Special 510(k) – 510(k) Summary of Safety and Effectiveness**

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

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

FDA Establishment Number 1038671

**Contact Person:** Zach Sharrah
Regulatory Affairs Specialist
Telephone: (352) 327-4674
Fax: (352) 378-2617

**Date:** February 13, 2017

**Proprietary Name:** Exactech® Equinoxe® Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap

**Common Name:** Reverse Shoulder Arthroplasty

**Classification Name:**

- Prosthesis, Shoulder, Non-Constrained, Metal/Polymer cemented (21 CFR Section 888.3650, Class II, Product Code KWT
- Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer cemented (21 CFR Section 888.3660, Class II, Product Code KWS
- Shoulder Prosthesis, Reverse Configuration (21 CFR Section 888.3660, Class II, Product Code PHX

**Legally Marketed Device to Which Substantial Equivalence Is Claimed:**

| Name | Manufacturer | 510(k) Number |
|---|---|---|
| Equinoxe Reverse Shoulder System | Exactech, Inc | K063569 |
| Equinoxe Reverse Shoulder | Exactech, Inc | K110708 |

**Indication for Use:**
The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

**Exactech® Equinoxe® Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap**
**Special 510(k) – 510(k) Summary of Safety and Effectiveness**

**Device Description:**
The proposed Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap devices represent a modification of the predicate Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap (K063569 and K110708) used in reverse shoulder arthroplasty. All devices were cleared via 510(k) K063569 except the 50mm and 54mm Equinoxe Reverse Shoulder Compression Screws. These sizes were cleared via 510(k) K110708. The only difference between the proposed Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap and predicate Equinoxe Compression Screws, Glenosphere Locking Screw, and Locking Cap is the sterilization method. The predicate compression screws, glenosphere locking screw, and locking cap are provided sterile via gamma radiation. The modified compression screws, glenosphere locking screw, and locking cap will be supplied non-sterile and must be sterilized by steam sterilization in a separately provided re-usable sterilization container prior to implantation. Cleaning and sterilization instructions are provided in the package insert for the Equinoxe Reverse Shoulder System Screw Components.

Both the predicate and modified devices share the following similarities:

- The same indications for use
- The same intended use
- The same materials
- The same design features and basic fundamental scientific technology
- The same dimensions
- The same device compatibility

**Testing:**
This submission references cleaning and sterilization assessments conducted to demonstrate substantial equivalence of the modified Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap to the predicate Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap.

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 modified Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap are substantially equivalent to the cited cleared Exactech Equinoxe Reverse Shoulder Compression Screws, Glenosphere Locking Screw, and Locking Cap predicate devices.