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

February 27, 2017

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

Re: K162903
Trade/Device Name: Exactech Equinoxe Humeral Reconstruction Prosthesis Extra-small Proximal Bodies
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder Joint Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, PHX, HSD
Dated: January 26, 2017
Received: January 30, 2017

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)*
K162903

Device Name
Exactech® Equinoxe® Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies

Indications for Use *(Describe)*
The Equinoxe Humeral Reconstruction 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 Humeral Reconstruction Prosthesis System can be used in either primary or revision arthroplasty procedures.

The Equinoxe Humeral Reconstruction 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 irreplaceable and grossly deficient, and a functional deltoid muscle is present.

In the USA, the Equinoxe Humeral Reconstruction Prosthesis System is not indicated for use with the Equinoxe Reverse Shoulder System components in oncology applications.

The Equinoxe Humeral Reconstruction Prosthesis Distal Stems are for cemented use only, while the HA coated Equinoxe Humeral Reconstruction Prosthesis Distal Stem Collars 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Exactech® Equinoxe® Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies
# 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:** January 26, 2017

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

**Proprietary Name:** Exactech® Equinoxe® Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies

**Common Name:** Humeral Stem

**Classification Name:**

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

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

| Name | Manufacturer | 510(k) Number |
|---|---|---|
| Equinoxe Humeral Reconstruction Prosthesis | Exactech, Inc | K143659 |

**Indication for Use:**

The Equinoxe Humeral Reconstruction 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

**Exactech® Equinoxe® Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies**
**Traditional 510(k) – 510(k) Summary**

- Oncology applications including bone loss due to tumor resection.
- Significant humeral resection which are unmanageable using other treatment methods

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

The Equinoxe Humeral Reconstruction 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 irreplaceable and grossly deficient, and a functional deltoid muscle is present.

In the USA, the Equinoxe Humeral Reconstruction Prosthesis System is not indicated for use with the Equinoxe Reverse Shoulder System components in oncology applications.

The Equinoxe Humeral Reconstruction Prosthesis Distal Stems are for cemented use only, while the HA coated Equinoxe Humeral Reconstruction Prosthesis Distal Stem Collars are only for uncemented, press-fit use.

**Device Description**
The proposed Exactech Equinoxe Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies represent a modification of the predicate Exactech Equinoxe Humeral Reconstruction Prosthesis Proximal Bodies cleared in K143659. Both the predicate and proposed devices have the same intended use, general design features and basic fundamental scientific technology. The only difference between the predicate and the proposed device is a decreased tuberosity thickness.

**Testing:**
An engineering analysis was conducted to evaluate the mechanical properties of the proposed Equinoxe Humeral Reconstruction Prosthesis Extra-Short Proximal Bodies, including:

- Taper Analysis
- Suture Abrasion
- Axial Pull-off
- Fatigue Testing
- Torsion 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:**
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Exactech Equinoxe Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies are substantially equivalent to the cleared Exactech Humeral Reconstruction Prosthesis Proximal Bodies.