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

November 2, 2016

Exactech, Incorporated
Lindy Knisely, RN
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K110708
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder System™
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: March 11, 2011
Received: March 14, 2011

Dear Ms. Knisely:

This letter corrects our substantially equivalent letter of April 1, 2011.

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,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Exactech® Equinoxe® Reverse Shoulder™ Line Extensions
Special 510(k) – Indications for Use

510(k) Number: K110708

Device Name(s): Exactech® Equinoxe® Reverse Shoulder System™

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
√	√		Congenital abnormalities in the skeletally mature
√			Primary and secondary necrosis of the humeral head.
√		√	Humeral head fracture with displacement of the tuberosities
√	√		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)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
√	√		To restore mobility from previous procedures (e.g. previous fusion)

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.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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CDRH/ODE concurrence on next page

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Exactech® Equinoxe® Reverse Shoulder™ Line Extensions
Special 510(k) – Indications for Use

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKenna

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110708

Exactech® Equinoxe® Reverse Shoulder™ Line Extensions
Special 510(k) - Section 07 - 510(k) Summary

I. Submitter Information

Company: Exactech, Inc
2320 N.W. 66th Court
Gainesville, Florida 32653

Date: March 11, 2011

Contact Person: Lindy Knisely, RN
Regulatory Affairs Specialist
Telephone: (352) 377-1140
Fax: (352) 378-2617

II. Device Information

Proprietary Name: Exactech Equinoxe® Reverse Shoulder™

Common Name: Laterally Offset Glenospheres
Posterior Augment Glenoid Plate
Superior Augment Glenoid Plate
Extended Cage Glenoid Plate
Compression Screws

Classification Name: Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented (21 CFR 888.3650 [Shoulder joint metal/polymer non-constrained cemented prosthesis], Class II, Product Code KWT)

Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented (21 CFR 888.3660 [Shoulder joint metal/polymer semi - constrained cemented prosthesis], Class II, Product Code KWS)

III. Legally Marketed Devices to Which Substantial Equivalence Is Claimed

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K063569	Exactech Equinoxe Reverse Shoulder	Exactech, Inc
K093275	Exactech Equinoxe Reverse Shoulder	Exactech, Inc.

IV. Device Description

The modifications proposed by this submission describe minor geometry changes to the standard offering of Equinoxe glenospheres, glenoid plates, and compression screws; these geometry modifications are the entire basis for proposed Reverse Shoulder line extensions (expanded offset glenospheres, posterior and superior augmented glenoid plates, +10mm extended cage glenoid plate, and longer compression screws).

All proposed components are designed to interface and articulate with the Equinoxe Shoulder system and are supplied sterile.

V. Indications Use

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- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

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√			Primary and secondary necrosis of the humeral head.
√		√	Humeral head fracture with displacement of the tuberosities
√	√		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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	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
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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.

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tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

VI. Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** Exactech Equinoxe Reverse Shoulder line extensions and predicate devices are intended for use in Total Shoulder Arthroplasty.
- **Materials.** Exactech Equinoxe Reverse Shoulder line extensions and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Exactech Equinoxe Reverse Shoulder line extensions and predicate devices are available in equivalent size ranges.
- **Sterilization processes.** Exactech Equinoxe Reverse Shoulder line extensions and predicate devices are provided sterile for single use and conform to recognized industry standards.
- **Performance specifications.** Exactech Equinoxe Reverse Shoulder line extensions and predicate devices withstand clinically relevant biomechanical loads.

Substantial Equivalence Conclusion

Mechanical tests, simulated-use tests, engineering analyses, and a clinical literature summary demonstrate the proposed Exactech Equinoxe Reverse Shoulder line extensions are substantially equivalent to the predicate devices. A summary of these tests and analyses are as follows:

- Cadaver lab validation demonstrating the design features.
- Geometric computer analysis to evaluate the relationship between the reverse shoulder design parameters and ROM, impingement, and stability.
- Dynamic test at worst case physiological load in a polyurethane bone substitute in order to evaluate initial fixation, loosening, and disassociation.
- Clinical literature summary related to cuff tear arthroplasty and reverse shoulder arthroplasty.