K113309

DEC - 8 2011

Exactech Equinoxe® Cage Glenoids™
Special 510(k) – 510(k) Summary of Safety and Effectiveness

I. **Sponsor:** Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653
Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Specialist

Date: November 28, 2011

II. **Proprietary Name:**
Exactech Equinoxe Cage Glenoids

Common Name:
Glenoid Component

Classification Name:
Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660, 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
K093430	Exactech Equinoxe Cage Glenoid	Exactech, Inc.

IV. **Device Description:**
This submission proposes modifying Exactech Equinoxe Cage Glenoid devices cleared via 510(k) #K093430 to change peg geometry and add plasma coating. The proposed Equinoxe Cage Glenoids are intended to be used with the same Equinoxe shoulder system components described in 510(k) #K042021 and 510(k) #K061454 as cited predicates.

V. **Intended Use of the Device**
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.

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- 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.

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VI. Rationale for Substantial Equivalence

Intended Use / Indications for Use. Both proposed and predicate devices have identical indications for use.

Materials. Both proposed and predicate devices are composed of identical biocompatible materials conforming to recognized industry standards for permanent implants. The only material difference is the addition of cp-titanium plasma coating on the central peg of the proposed devices.

Design Features. Both proposed and predicate devices have the same key design features, including articulating geometry and fixation.

Dimensions. Both proposed and predicate devices have identical geometry for mating with the same Equinoxe humeral stems and heads. The only dimensional difference is a change to the length and diameter of the glenoid pegs and associated locking mechanisms of the proposed devices.

Packaging and Sterilization. Both proposed and predicate devices are packaged and sterilized using the same materials and processes.

Device Shelf Life. Proposed and predicate devices have the same shelf life.

Fixation Method: Proposed and predicate devices use the same cemented-only fixation method, where bone cement is applied to cover the entire back of the glenoid component and the peg, keel, and cage, and cage augment features are also fully cemented.

VII. Summary of Non-Clinical Performance Data

- Mechanical glenoid loosening/disassociation testing per ASTM F2028
- Mechanical testing for axial disassembly of modular pegs
- Mechanical testing for resistance of locking mechanism to shear and bending
- Plasma coating shear fatigue strength testing per ASTM F1160
- Plasma coating static shear strength testing per ASTM F1044
- Plasma coating static tensile strength testing per ASTM F1147
- Plasma coating abrasion testing per ASTM F1978

VIII. Substantial Equivalence Conclusion

Test results and analyses provided in this submission demonstrate the proposed Equinoxe Cage Glenoids are substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Mr. Patrick Hughes
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32605

DEC - 8 2011

Re: K113309
Trade/Device Name: Exactech Equinoxe Cage Glenoids
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: November 7, 2011
Received: November 8, 2011

Dear Mr. Hughes:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech Equinoxe® Cage Glenoids™
Special 510(k) – Indications for Use

510(k) Number: K113309

Device Name: Exactech Equinoxe Cage Glenoids

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.

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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,

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Special 510(k) – Indications for Use

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K113309