K093430 Summary of S&E p. 1/4

I. Submitter Information

Company: Exactech, Inc
2320 NW 66th Court
Gainesville, FL 32653
800-392-8711

SEP 2 2010

Date: August 31, 2010

Contact Person: Graham L. Cuthbert Regulatory Affairs Specialist II

II. Device Information

Proprietary Name: Exactech Equinoxe® Cage Glenoid™
Exactech Equinoxe® XL Keeled & XL Pegged Glenoid

Common Name: Glenoid Component

Classification Name: Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650, Class II, Product Code KWT)
Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented (21 CFR 888.3660, Class II, Product Code KWS)

III. Legally Marketed Devices to Which Substantial Equivalence Is Claimed

Exactech Equinoxe Cage Glenoid

- Depuy Anchor Peg Glenoid #K981487
- Tornier Affiniti Glenoid #K081707
- Smith and Nephew Cofield Glenoid: #K955767 and #K070565.
- Biomet Modular Hybrid Glenoid: #K060694

Exactech Equinoxe XL Keeled and XL Pegged Glenoid

- Exactech Equinoxe Glenoids: #K042021
- Tornier Aequalis Glenoids: #K994393
- Depuy Global Glenoids: #K981487

IV. Device Description

The Equinoxe Shoulder System comprises both cemented and press-fit semi-constrained glenohumeral prostheses for use in hemi-shoulder and total-shoulder joint replacement procedures and a cemented semi-constrained glenohumeral fracture prosthesis for use in fractures of the proximal humerus. The system includes various sizes and types of modular humeral stems, humeral heads, glenoids, replicator plates, and screws for use in primary, revision, and fracture applications.

Exactech Equinoxe Cage Glenoid

The Equinoxe Caged Glenoids are designed to interface and articulate with the Equinoxe total-shoulder system. They are composed of an Ultra High Molecular Weight Polyethylene (UHMWPE) articulating surface modularly connected to a grit blasted titanium (Ti-6Al-4V) bone cage and three grit blasted titanium (Ti-6Al-4V) pegs. A posterior augment version of

this cage glenoid is provided to preserve bone by limiting the amount of eccentric glenoid reaming necessary to correct the patient's glenoid version. All components are supplied sterile.

Exactech Equinoxe XL Keeled an XL Pegged Glenoid

The Equinoxe XL Keeled and XL Pegged Glenoids are designed to interface and articulate with the 47, 50, & 53 mm humeral head from the Equinoxe total-shoulder system. The subject devices are a modification of the previously cleared Equinoxe cemented keeled and pegged glenoids (#K042021). All components are supplied sterile.

Additionally, this "Traditional" 510(k) proposes several modifications to our previously cleared Equinoxe cemented keeled and pegged glenoids. Specifically: 1) an addition of an XL keeled and pegged glenoid size, 2) a decrease in minimum UHMWPE thickness from 5mm to 4mm, 3) a modification in machining pattern on the backside surface (change from horizontal grooves to radial grooves that follow the profile of the device), and 4) a decrease in edge radius around each fixation surface from 0.047 inches to 0.031 inches.

V. Indications Use

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/R) and FRACTURE (F) humeral components are as follows:

P	L/R	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.

VI. Summary of Technological Characteristics

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

Exactech Equinoxe Cage Glenoid

- **Intended Use.** Exactech Equinoxe Cage Glenoids and predicate devices are intended for use in Total Shoulder Arthroplasty. The Equinoxe cage glenoids and posterior augment cage glenoids are intended for cemented fixation.
- **Materials.** Exactech Equinoxe Cage Glenoids and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Exactech Equinoxe Cage Glenoids and predicate devices are available in equivalent size ranges.
- **Sterilization processes.** Exactech Equinoxe Cage Glenoids and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Exactech Equinoxe Cage Glenoids and predicate devices conform to recognized performance standards for total shoulder joint replacement devices.

Exactech Equinoxe XL Keeled and XL Pegged Glenoid

- **Intended Use**. Exactech Equinoxe XL Keeled, XL Pegged Glenoid and predicate devices are intended for use in Total Shoulder Arthroplasty. The XL keeled and pegged glenoids are intended for cemented fixation.
- **Materials.** Exactech Equinoxe XL Keeled, XL Pegged Glenoid and predicate devices composed of equivalent materials conforming to recognized industry standards for permanent implants.

- **Dimensions.** Exactech Equinoxe XL Keeled, XL Pegged Glenoid and predicate devices are available in equivalent size ranges.
- **Sterilization processes.** Exactech Equinoxe XL Keeled, XL Pegged Glenoid and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Exactech Equinoxe XL Keeled, XL Pegged Glenoid and predicate devices conform to recognized performance standards for total shoulder joint replacement devices.

Summary of Non-Clinical Performance Data

Literature reviews, finite element analyses, mechanical tests (edge loading and displacement studies, wear, thermal expansion and disassembly force), engineering analyses, biocompatibility studies and simulated surgical (sawbones and cadaver) implantations were conducted to demonstrate the safety and effectiveness of the Exactech Equinoxe Cage Glenoids, the Exactech Equinoxe XL Keeled and XL Pegged Glenoids in support of the claim of substantial equivalence to the predicates listed above.

Substantial Equivalence Conclusion

Results from these tests and analyses provided within this 510(k) demonstrate that the Exactech Equinoxe Cage Glenoids, XL Keeled glenoids, XL Pegged Glenoids and the modified cemented keeled and pegged glenoids are substantially equivalent to the identified predicate devices.

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. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 NW 66th Court
Gainesville, Florida 32653

SEP 2 2010

Re: K093430
Trade/Device Name: Exactech Equinoxe XL Keeled, XL Pegged and Cage Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, KWT
Dated: August 19, 2010
Received: August 24, 2010

Dear Mr. Cuthbert:

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

K093430

p. 1/2

Exactech®, Inc.
Indications for Use

510(k) Number: _____

Device Name: Exactech Equinoxe® XL Keeled, XL Pegged and Cage Glenoid™

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	√		spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
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Prescription Use __X__ or Over-the-counter Use _____
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K093430

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

510(k) Number _____