

K121220

**Exactech® Equinox® UHMWPE 16° Posterior Augment Pegged Glenoids™
Special 510(k) – 510(k) Summary of Safety and Effectiveness**

NOV 20 2012

I. Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653
Phone: (352) 377-1140
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FDA Establishment Number 1038671

Contact: Graham L Cuthbert
Regulatory Affairs Specialist II

Date: April 19, 2012

II. Proprietary Name:
Exactech Equinox UHMWPE 16° Posterior Augment Pegged 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:

<u>510(k) Number</u>	<u>Trade or Proprietary or Model Name</u>	<u>Manufacturer</u>
K111379	Exactech Equinox UHMWPE 12 Degree Posterior Augment Pegged Glenoid	Exactech, Inc.

IV. Device Description:
This submission proposes an increase in the angled surface from 12° to 16°, relative to the 12° posterior augment pegged glenoid devices previously cleared via 510(k) K111379. The proposed Exactech Equinox Posterior Augment Glenoids are intended to be used with Equinox shoulder system components described in #K042021, #K061454, #K093430, #K103419, and #K111379.

V. Intended Use of the Device
The Equinox Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemiarthroplasty is determined by the surgeon to be the preferred method of treatment.

The cemented primary humeral stem, long/revision stem, fracture stems and all Equinox 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:

√	√		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. Rationale for Substantial Equivalence

- **Intended Use / Indications for Use.** The proposed and predicate devices are intended for use in total shoulder joint replacement and have identical indications for use.
- **Materials.** The proposed and predicate devices are composed of identical biocompatible materials conforming to recognized industry standards for permanent implants.

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- **Design Features.** The proposed and predicate devices have the same design features, including articulating geometry and fixation.
- **Dimensions.** The proposed and predicate devices have identical geometry for mating with previously cleared humeral stems and humeral heads. The only dimensional difference is an increase in the angled surface from 12° to 16°.
- **Packaging and Sterilization.** The proposed and predicate devices are packaged and sterilized using the same materials and processes.
- **Device Shelf Life.** The proposed and predicate devices have the same shelf life.

VII. Summary of Non-Clinical Performance Data

Mechanical testing per ASTM F2028 - Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation was conducted to demonstrate the safety and effectiveness of the proposed posterior augment glenoids in support of the claim of substantial equivalence to the predicate device.

Cyclic Shear and Shear Load to Failure testing was conducted to demonstrate the safety and effectiveness of the proposed posterior augment glenoids in support of the claim of substantial equivalence to the predicate device

Substantial Equivalence Conclusion

Test result and analyses provided in this 510(k) demonstrate the proposed Exactech Equinox Posterior Augment Glenoids are substantially equivalent to the cited predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 20, 2012

Exactech, Incorporated
% Mr. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K121220

Trade/Device Name: Exactech[®] Equinox[®] UHMWPE 16° Posterior Augment Pegged
Glenoids[™]

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: KWS

Dated: October 15, 2012

Received: October 22, 2012

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" (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 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,

Erin I. Keith

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

Enclosure

**Exactech® Equinox® UHMWPE 16° Posterior Augment Pegged Glenoids™
Special 510(k) – Indications for Use**

510(k) Number: K121220

Device Name: Exactech® Equinox® UHMWPE 16° Posterior Augment Pegged Glenoids

The Equinox 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 Equinox 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

P	L	F	
√	√		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 Equinox 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 Equinox 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 Equinox 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

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Equinox 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 Equinox 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)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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