



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2016

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

Re: K102951

Trade/Device Name: Equinoxe Fixed-Angle Replicator Plates, Cast Humeral Heads, and
Cast Glenspheres

Regulation Number: 21 CFR 888.3660

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

Regulatory Class: Class II

Product Code: PHX, KWT, KWS

Dated: October 1, 2010

Received: October 5, 2010

Dear Mr. Cuthbert:

This letter corrects our substantially equivalent letter of November 4, 2010.

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

**Exactech® Equinoxe® Total Shoulder – Fixed Angle Replicator Plates,
Cast Humeral Heads, and Cast Glenospheres
Special 510(k) – Indications for Use**

NOV - 4 2010

510(k) Number (if known): K102951

Device Name: Equinoxe Fixed-Angle Replicator Plates, Cast Humeral Heads, and Cast Glenospheres.

INDICATIONS FOR 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 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 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	Indication
	✓	✓		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)
Stock Number			✓	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)

Mark M. Miller
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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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

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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 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)

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonathan J. Fox M.D.
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102951

**Exactech® Equinox® Total Shoulder – Fixed Angle Replicator Plates,
Cast Humeral Heads, and Cast Glenospheres
Special 510(k) – Substantial Equivalence**

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

Phone: (352) 377-1140
Fax: (352) 378-2617

NOV - 4 2010

Contact Person: Graham L. Cuthbert, Regulatory Affairs Specialist II

Date: October 1st, 2010

II. Proprietary Name: Exactech Equinox Fixed Angle Replicator Plate
Exactech Equinox Humeral Heads
Exactech Equinox Glenosphere

Common Name: Total Shoulder Prosthesis
Reverse Total Shoulder Prosthesis

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:

<u>510(k) Number</u>	<u>Trade or Proprietary Model Name</u>	<u>Manufacturer</u>
K042021	Equinox Total Shoulder System	Exactech, Inc
K063569	Equinox Reverse Total Shoulder System	Exactech, Inc

IV. Device Description:

The Equinox Shoulder System is comprised of primary, fracture and reverse product lines for use in hemi- and total-shoulder joint replacement procedures. The Equinox Primary and Fracture system utilize 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 Equinox Reverse Shoulder System includes a reverse semi-constrained prosthesis for use in total-shoulder joint replacement procedures in cases with an irreparable or nonfunctional rotator cuff. The Equinox Reverse Shoulder System is designed to function with the Equinox primary press-fit, primary cemented, and long/revision humeral stems.

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Special 510(k) – 510(k) Summary of Safety and Effectiveness**

The proposed fixed angle replicator plates are manufactured from wrought titanium alloy (Ti-6Al-4V E.L.I) per ASTM F136 and connect to the humeral stem via a spherical bowl and are locked in place using the previously cleared primary torque-defining screw. The replicator plate attaches to the humeral head using a morse taper. The mating features on the proposed replicator plates (specifically the morse taper geometry and the spherical bowl geometry) are identical to the predicate part, only the offset and angular adjustability have been altered.

The proposed humeral heads are manufactured from Cast Cobalt-Chrome Alloy (Co-28Cr-6Mo) per ASTM F75 and provide an articulating surface for hemi and total joint replacement. They feature female taper geometry for mating with proposed and predicate replicator plate designs. No design changes have been made to this device. It is a material change only.

The proposed glenospheres are manufactured from Cast Cobalt-Chrome Alloy (Co-28Cr-6Mo) per ASTM F75 and connect to the plate via an apical hole screw and slip fit with oval shaped plate. No design changes have been made to this device. It is a material change only.

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.
- 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

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P	L/R	F	Indications
	√		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

Equinoxe Fixed Angle Replicator Plate:

- **Intended Use / Indications for Use.** The Equinoxe Fixed Angle Replicator Plates and predicate devices are intended for use in total shoulder joint replacement and have identical indications for use.
- **Materials.** The Equinoxe Fixed Angle Replicator Plates and predicate devices are composed of equivalent biocompatible materials conforming to recognized industry standards for permanent implants.
- **Design Features.** The Equinoxe Fixed Angle Replicator Plates and predicate devices have the same design features.
- **Dimensions.** The Equinoxe Fixed Angle Replicator Plates and predicate devices have identical geometry for mating with the previously cleared humeral stems and humeral heads. The only difference is a new offset option and a reduction in the through hole diameter to prevent angulation of the plate. This has no effect on the mechanical strength of the design.
- **Packaging and Sterilization.** The Equinoxe Fixed Angle Replicator Plates and predicate devices are packaged and sterilized using the same materials and processes.
- **Device Shelf Life.** The Equinoxe Fixed Angle Replicator Plates and predicate devices have the same shelf life.

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Cast Humeral Heads:

- **Intended Use / Indications for Use.** The Equinox Cast Humeral Heads and predicate devices are intended for use in total shoulder joint replacement and have identical indications for use.
- **Materials.** The Equinox Cast Humeral Heads and predicate devices are composed of Co-28Cr-6Mo Alloys which are biocompatible materials conforming to recognized industry standards for permanent implants.
- **Design Features.** The Equinox Cast Humeral Heads and predicate devices have the same design features.
- **Dimensions.** The Equinox Cast Humeral Heads and predicate devices have identical geometry.
- **Packaging and Sterilization.** The Equinox Cast Humeral Heads and predicate devices are packaged and sterilized using the same materials and processes.
- **Device Shelf Life.** The Equinox Cast Humeral Heads and predicate devices have the same shelf life.

Cast Glenospheres:

- **Intended Use / Indications for Use.** The Equinox Cast Glenospheres and predicate devices are intended for use in reverse total shoulder joint replacement and have identical indications for use.
- **Materials.** The Equinox Cast Glenospheres and predicate devices are composed of Co-28Cr-6Mo Alloys which are biocompatible materials conforming to recognized industry standards for permanent implants.
- **Design Features.** The Equinox Cast Glenospheres and predicate devices have the same design features.
- **Dimensions.** The Equinox Cast Glenospheres and predicate devices have identical geometry.
- **Packaging and Sterilization.** The Equinox Cast Glenospheres and predicate devices are packaged and sterilized using the same materials and processes.
- **Device Shelf Life.** The Equinox Cast Glenospheres and predicate devices have the same shelf life.

VII. Summary of Non-Clinical Performance Data

Fatigue testing was conducted to verify the safety and effectiveness of the proposed Exactech Equinox Fixed Angle Replicator Plates, Cast Humeral Heads, and Cast Glenospheres. These tests were done to mitigate the risks that were affected by the proposed changes. Risks that were not affected by the new design were not re-verified.

Substantial Equivalence Conclusion

Results from these tests and analyses provided within this 510(k) demonstrate that the Exactech Equinox Fixed Angle Replicator Plates, Cast Humeral Heads, and

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Cast Glenospheres are substantially equivalent to the identified predicate devices and will be safe for clinical use.