Exactech

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K063569

510(k) Summary

FEB 23 2007

Company:	Exactech, Inc
Date:	November 28, 2006
Contact Person:	Amnon Talmor, Regulatory Affairs Representative
Proprietary Name:	Exactech Equinoxe™ Reverse Shoulder System
Common Name:	Reverse 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)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Depuy Delta III Reverse Shoulder (#K021478, #K050315, #K062116)
- Tornier Reverse Shoulder (#K030941, #K041873, #K050316)
- Zimmer BF Reverse Shoulder (#K052906, #K060704)
- Zimmer Anatomica Reverse Shoulder (#K053274)
- Encore Reverse Shoulder (#K041066, #K051075, #K052086)

Device Description

The Equinoxe™ 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 system includes primary and revision humeral stems, various sizes and types of humeral adapter plates, glenospheres, humeral liners, and screws. The reverse shoulder System is designed to function with the Equinoxe primary press-fit, primary cemented, and long/revision humeral stems. All components are supplied sterile.

Indications for Use

The Exactech Equinoxe™ Reverse Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe™ Reverse Shoulder System is also indicated for failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Summary of Technological Characteristics

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

- **Intended Use.** Equinoxe™ Reverse Shoulder System and predicate devices are intended for use in total reverse shoulder joint replacement and have similar indications for use statements.

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- **Materials.** Equinoxe™ Reverse Shoulder System and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Equinoxe™ Reverse Shoulder System and predicate device components are available in equivalent size ranges.
- **Sterilization processes.** Equinoxe™ Reverse Shoulder System and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Equinoxe™ Reverse Shoulder System and predicate devices conform to recognized performance standards for total shoulder joint replacement devices.

Summary of Non-Clinical Performance Data

Mechanical tests, engineering analyses, and simulated surgical (sawbones and cadaver) implantations were conducted to demonstrate the safety and effectiveness of the devices that compose the Equinoxe™ Reverse Shoulder System and support the claim of substantial equivalence to the predicates listed above; a summary of these tests and analyses are as follows:

- A dynamic loading study in which the stability of the Equinoxe Reverse Shoulder was assessed in a polyurethane bone substitute (TR-2006-052) and in a cadaver (TS-2006-024). The glenoid plate/glenosphere micromotion measurements obtained in this study are compared to that associated with the Depuy Delta III and Encore RSP components when subjected to a similar loading pattern.
- A comparative assessment of the glenosphere center of rotation that demonstrates the location of the center of rotation is similar for the Equinoxe and Delta III designs. This observation in conjunction with the micromotion test results (TR-2006-052 and TS-2006-024) suggest that the low reported incidence of glenoid loosening associated with the Grammont Reverse Shoulder is applicable to the Equinoxe™ Reverse Shoulder design (TR-2006-053).
- A geometric analysis of the Grammont Reverse Shoulder Prosthesis—an evaluation of the relationships between prosthetic design parameters and clinical failure modes (TR-2006-028). This assessment was used to optimize the design parameters associated with the Equinoxe design in order to maximize ROM and minimize inferior impingement.
- A geometric analysis verification study that demonstrates the Equinoxe Reverse Shoulder achieves an increase in the amount of motion and a decrease in the amount of inferior impingement (a measure of motion and stability, indicative of scapular notching) while maintaining a similar amount of jump distance (a measure of stability, indicative of the probability of dislocation) relative to the Grammont/Delta III design (TR-2006-029).
- A finite element analysis that demonstrates the geometry of the proposed devices is not subject to fracture when subjected to a worst-case load (TR-2006-039).

Substantial Equivalence Conclusion

Results from mechanical tests and engineering analyses provided within this 510(k) demonstrate that the Equinoxe™ Reverse Shoulder System is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exactech, Inc
% Mr. Amnon Talmor
Regulatory Affairs Representative
2320 NW 66th Court
Gainesville, Florida 32653

FEB 23 2007

Re: K063569
Trade/Device Name: Equinoxe Reverse Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWT
Dated: November 27, 2006
Received: November 29, 2006

Dear Mr. Talmor:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchman TA

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063569

Exactech®, Inc.

Indications for Use

510(k) Number (if known):

Device Name: Equinoxe Reverse Shoulder System

INDICATIONS FOR USE:
The Exactech Equinoxe™ Reverse Shoulder System is indicated to relieve pain and restore function 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 failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

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 General, Restorative, and Neurological Devices

510(k) Number K063569