1-63

2320 NW 66TH COURT
GAINESVILLE, FL 32653
352 377 1140
FAX 352 378 2617

OCT 2 6 2004

K042021

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

2. Contact: Dr. Gary Miller
Executive Vice President of Research and Development
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653
Phone: (352) 377-1140
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3. Product: Exactech Equinoxe® Shoulder System

21 CFR Section 888.3660
Product Code 87 KWS
Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Cemented

21 CFR Section 888.3690
Product Code 87 HSD
Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Cemented or Uncemented

Class II

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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.

Intended Use:

The cemented primary humeral stem, long/revision stem, fracture stem, and both the pegged and keeled glenoids are intended for cemented fixation only. The press-fit stems are intended for press-fit applications but may be used with bone cement if deemed appropriate by the surgeon. The long/revision stem is advised when the distal bone quality is insufficient to adequately anchor the primary stems (typically as a result of mid-humeral fractures). The fracture stem is advised for 3 & 4 part fractures of the proximal humerus. All components are supplied sterile.

Technological Characteristics and Substantial Equivalence:

The devices that compose the Equinoxe® Shoulder System are manufactured from similar materials and have similar design features as competitive devices that have been demonstrated to be safe and effective for equivalent indications.

Specifically, the Equinoxe® press-fit humeral stems are substantially equivalent to the Tornier Aequalis (K980244), the Zimmer (Sulzer) Anatomica (K003801), the Plus Orthopedic PROMOS (K032126), and the Arthrex (K010124) press-fit humeral stems. The Equinoxe® cemented humeral (short & long) stems are substantially equivalent to the Plus Orthopedic PROMOS (K032126), the Depuy Global (K992065), and the Arthrex (K010124) press-fit humeral stems. The Equinoxe® fracture humeral stems are substantially equivalent to the Tornier Fracture (K994392, K003728, K032679), and the Depuy Global FX (K011099 & K984541) fracture humeral stems. The modular eccentric humeral heads are substantially equivalent to the Depuy Global (K974044 & K992065), the Stryker Howmedica Osteonics Solar (K001419), the Tornier Aequalis (K012212), and the Zimmer (Sulzer) Anatomica (K990137) eccentric humeral heads. Finally, the Equinoxe® cemented pegged and keeled glenoids are substantially equivalent to the Tornier Aequalis (K994393), the Encore Foundation (K960906), the Plus Orthopedic PROMOS (K032126), the Zimmer (Sulzer) Anatomica (K990136), and the Depuy Global (K981487) cemented glenoids.

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Performance Testing:

A number of mechanical tests and engineering analyses were conducted to demonstrate the safety and efficacy of the devices that compose the Equinoxe shoulder system. Test reports detail: 1) the design rationale for each of the devices that compose the Equinoxe shoulder system; 2) the methodology used to demonstrate how these devices were determined to be safe and effective; 3) the results from these mechanical tests and engineering analyses, and 4) the interpretations of the data. Collectively, the reports demonstrate the devices that compose the Equinoxe shoulder system perform as intended and are substantially equivalent to the predicate devices referenced in this submission.

Conclusions:

The Exactech Equinoxe® Shoulder System is substantially equivalent to currently marketed devices with similar indications for use. A comparison of design features, implant scope, critical dimensions, and manufacturing materials indicate that the proposed system has similar fundamental scientific technology and the same intended use as the referenced predicate devices. The safety of the proposed system is further demonstrated by the results of numerous mechanical tests and engineering analyses that have been reported in this submission; collectively, these reports demonstrate the effectiveness of the design. For these reasons, we conclude the Equinoxe® Shoulder System is safe and effective when used as intended.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Dr. Gary Miller
Executive Vice President of Research and Development
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K042021
Trade/Device Name: Exactech Equinoxe® Shoulder System
Regulation Number: 21 CFR 888.3660, 21 CFR 888.3690
Regulation Names: Shoulder joint metal/polymer semi-constrained cemented prosthesis;
Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Codes: KWS, HSD
Dated: July 27, 2004
Received: July 28, 2004

Dear Dr. Miller:

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.

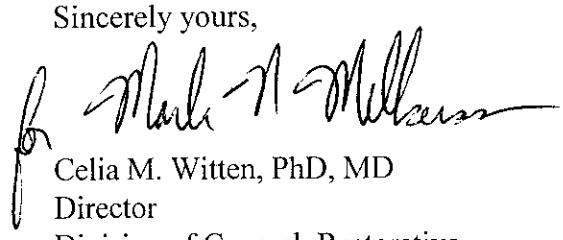
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(1 of 1)

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Indications for Use Statement

510(k) Number: K042021

Device Name: **Exactech Equinoxe® Shoulder System**

The Equinoxe Shoulder System is indicated to relieve pain and restore function 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.

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 arthodesis 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)

Prescription Use X or Over-the-counter Use _____
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millerman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042021

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