2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

K061454

Exactech, Inc.®
Equinoxe® Shoulder Stem Size Scope Extension
Special 510(k)
Summary of Safety and Effectiveness

JUN 12 2006

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

2. Contact: Chris Roche
Product Development Engineer
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653
Phone: (352) 377-1140
Fax: (352) 378-2617

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

Exactech

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

Exactech, Inc.®
Equinoxe® Shoulder Stem Size Scope Extension
Special 510(k)
Summary of Safety and Effectiveness

Trade or Proprietary or Model Name(s):
Equinoxe Press-Fit Primary Humeral Stems (size17x125 and 19x130)
Equinoxe Cemented Revision Humeral Long Stems (size 10x200mm, 12x200mm)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
#K042021	Equinoxe Press-Fit Primary Humeral Stems (Size 7x100mm, 9x105mm, 11x110mm, 13x115mm, 15x120mm)	Exactech, Inc.
#K042021	Equinoxe Cemented Revision Humeral Long Stems (Size 8x175mm, 8x215mm)	Exactech, Inc.

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.

Special 510(k) Modifications:

- Addition of 17 x 125 and 19 x 130mm Press-Fit Primary Humeral Stem size
- Addition of 10 x 200 and 12 x 200 Cemented Revision Humeral Long Stems
- Increased lateral offset for sizes 11,12,13,15

Conclusions:

Engineering evaluations were conducted verifying the proposed Equinoxe Press-Fit Humeral Stems and the Equinoxe Cemented Revision Humeral Long Stems are appropriate for anticipated *in vivo* use and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

Exactech, Inc.
% Ms. Maritza Elias
Regulatory Representative
2320 NW 66th Court
Gainesville, Florida 32653

Re: K061454
Trade/Device Name: Exactech Equinoxe® Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: April 24, 2006
Received: May 25, 2006

Dear Ms. Elias:

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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Exactech, Inc.®
Equinoxe® Shoulder Stem Size Scope Extension
Special 510(k)
Indications for Use

510(k) Number: _____

INDICATIONS FOR USE

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** _____

(Division Sign-Off)

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

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

06/06/06

510(k) Number K061454