DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Exactech, Incorporated
Shing Jen Tai, PhD
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K082702
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder System +15 mm Humeral Adapter Tray
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: September 12, 2008
Received: September 16, 2008

Dear Dr. Tai:

This letter corrects our substantially equivalent letter of October 10, 2008.

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® Reverse Shoulder System +15mm Humeral Adapter Tray
Special 510(k) – Indications for Use

Indications for Use Statement

510(k) Number: K082702

Device Name: Exactech® Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray

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)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division
Division Restorative,
and Neurological Devices

Section
K082702

K082202

Exactech® Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray
Special 510(k) – 510(k) Summary of Safety and Effectiveness

OCT 10 2008

510(k) Summary of Safety and Effectiveness

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, FL 32653

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

FDA Establishment Number 1038671

Contact: **Shing Jen Tai, PhD**
Regulatory Affairs Specialist

Date: **September 12, 2008**

Trade or Proprietary or Model Name(s):
Exactech® Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray

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)

Information on devices to which Substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K063569	Equinoxe® Reverse Shoulder System	Exactech, Inc.

Exactech® Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray
Special 510(k) – 510(k) Summary of Safety and Effectiveness

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.

Device Description:
The proposed Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray is a modification to the existing Equinoxe® Reverse Shoulder System humeral adapter tray devices previously cleared in K063569. The +15mm humeral adapter tray mates with previously cleared Equinoxe® primary press-fit, primary cemented, and cemented revision/long humeral stems (K042021) and the Equinoxe® reverse shoulder components (K063569). The rationale for the device line extension is to offer an additional size of offset to tension the deltoid and provide stability.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:
- the same indications for use
- the same design features
- incorporate the same materials
- the same shelf life
- are packaged and sterilized using the same materials and processes.

The only modification to the predicate device consists of a proposed dimensional change to increase the thickness of the humeral adapter tray to provide a +15mm offset.

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate that the Exactech® Equinoxe® Reverse Shoulder System +15mm Humeral Adapter Tray is substantially equivalent to the cleared predicate devices.