October 12, 2018

Exactech, Inc.
Zach Sharrah
Senior Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K182536
Trade/Device Name: Exactech Equinoxe Small Reverse Shoulder Glenospheres , Exactech Equinoxe Reverse Shoulder Humeral Liners , Exactech Equinoxe Small Reverse Shoulder Glenoid Plates , Exactech Equinoxe Reverse Shoulder Locking Cap
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: September 13, 2018
Received: September 14, 2018

Dear Zach Sharrah:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S
Digitally signed by Vesa Vuniqi -S
Date: 2018.10.12 15:21:00 -04'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182536

Device Name

Exactech® Equinoxe® Small Reverse Glenospheres and Humeral Liners

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Exactech® Equinoxe® Small Reverse Glenospheres and Humeral Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Sponsor: Exactech®, Inc.
2320 NW 66th Court
Gainesville FL, 32653

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

FDA Establishment Number 1038671

Contact Person: Zach Sharrah
Senior Regulatory Affairs Specialist
Telephone: (352) 377-1140
Fax: (352) 378-2617

Date: September 13, 2018

Proprietary Name: Exactech® Equinoxe® Small Reverse Glenospheres and Humeral Liners

Common Name: Reverse Shoulder Arthroplasty

Classification Name:

- Shoulder Prosthesis, Reverse Configuration (21 CFR Section 888.3660, Class II, Product Code PHX
- Prosthesis, Shoulder, Non-Constrained, Metal/Polymer cemented (21 CFR Section 888.3650, Class II, Product Code KWT
- Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer cemented (21 CFR Section 888.3660, Class II, Product Code KWS

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Equinoxe Small Reverse Shoulder System	Exactech, Inc.	K180632
Equinoxe Reverse Shoulder	Exactech, Inc.	K063569

Indications for Use:
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.

Exactech® Equinoxe® Small Reverse Glenospheres and Humeral Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Device Description:
The Exactech Equinoxe Small Reverse Shoulder is a subsystem of the Exactech Equinoxe Reverse Shoulder System which provides small reverse glenoid plates, small reverse glenospheres, screw components, humeral liners, and surgical instrumentation for use in reverse total shoulder arthroplasty. The modifications proposed by this submission describe minor geometry changes to the predicate Exactech Equinoxe Small Reverse Shoulder Glenospheres and Humeral Liners. As well as minor geometry modifications, this submission proposes Equinoxe Locking Cap compatibility with the Small Reverse Glenoid Plates and Small Reverse Glenospheres.

Both the proposed and predicate devices share the following similarities:

- Identical Indications for Use
- Identical intended use
- Identical device materials
- The same design features and basic fundamental scientific technology
- The same implant and instrument compatibility

Non-Clinical Testing:
Engineering and tolerance analyses were conducted to evaluate the mechanical and dimensional properties of the Exactech Equinoxe Small Reverse Glenospheres and Equinoxe Locking Cap compatibility:

- TM-2018-0755 – Justification for the Equinoxe Small Reverse Shoulder Glenosphere Internal Bore Modification and Standard Locking Cap Compatibility
- TR-2018-0720 – Equinoxe Small Reverse Shoulder Glenosphere, Glenosphere Trial, and Locking Cap Tolerance Analysis
- TM-2018-0523 – Justification for the Humeral Liner Undercut Geometry Tolerance Update

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Equinoxe Small Reverse Shoulder components meet recommended limits per FDA's *Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile*.

Substantial Equivalence Conclusion:
Results of the engineering analyses referenced in this 510(k) submission demonstrate the proposed Equinoxe Small Reverse Glenosphere and Humeral Liner devices are substantially equivalent to the cited cleared predicate Equinoxe Small Reverse Glenosphere and Humeral Liner devices.