February 20, 2020

Exactech®, Inc
Zach Sharrah
Manager, Regulatory Affairs
2320 NW 66th Court
GAINESVILLE, FL 32653

Re: K193098
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder Glenospheres
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: January 17, 2020
Received: January 21, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K193098

Device Name
Exactech® Equinoxe® Reverse Shoulder Glenospheres

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exactech® Equinoxe® Reverse Shoulder Glenospheres
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
Manager, Regulatory Affairs
Telephone: (352) 377-1140
Fax: (352) 378-2617

Date: November 6, 2019

Proprietary Name: Exactech® Equinoxe® Reverse Shoulder Glenospheres

Common Name: Reverse Shoulder Arthroplasty

Classification Name:

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

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Equinoxe Reverse Shoulder System	Exactech, Inc.	K063569
Equinoxe Reverse Shoulder System 36mm Glenosphere and Humeral Liners	Exactech, Inc.	K093275
Equinoxe Reverse Shoulder Line Extensions	Exactech, Inc.	K110708
Equinoxe Reverse Shoulder 46x21mm Glenosphere	Exactech, Inc.	K150458

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® Reverse Shoulder Glenospheres
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Device Description:
The Exactech Equinoxe Reverse Shoulder Glenospheres and Extended Locking Cap are for use in reverse total shoulder arthroplasty. The modifications proposed by this submission describe minor geometry changes to the predicate Exactech Equinoxe Glenospheres and Locking Cap; these geometry modifications are the entire basis for the proposed devices.

Both the proposed and predicate devices share the following similarities:

- Identical Indications for Use
- Identical intended use
- Identical materials
- Identical Equinoxe implant mating compatibility (baseplate, compression screw, glenosphere locking screw, and humeral liner)
- The same design features and basic fundamental scientific technology

Non-Clinical Testing:
The following non-clinical testing and engineering analyses were performed to demonstrate that the Exactech Equinoxe Reverse Shoulder Glenospheres and Extended Locking Cap perform as intended and are substantially equivalent to the identified predicate devices:

- Equinoxe Glenoid Plate Fixation Testing in accordance with ASTM F2028 for Reverse Total Shoulder Arthroplasty
- Equinoxe Glenoid Plate/ Glenosphere Fixation Testing in accordance with ASTM F2028 for Reverse Total Shoulder Arthroplasty
- Range of Motion Evaluation of the Equinoxe Reverse Shoulder Glenospheres in accordance with ASTM F1378

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Equinoxe Reverse Shoulder Glenospheres 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 engineering studies referenced in this 510(k) submission demonstrate the proposed Equinoxe Reverse Shoulder Glenospheres and Extended Locking Cap devices are substantially equivalent to the cited cleared predicate Equinoxe implants.