Exactech, Inc.
Zach Sharrah
Manager, Regulatory Affairs
2320 NW 66th Court
GAINSVILLE, FL 32653

April 29, 2020

Re: K192097
Trade/Device Name: Exactech® Equinoxe® Stemless Humeral Components
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: March 26, 2020
Received: March 30, 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)*

K192097

Device Name
Exactech® Equinoxe® Stemless Humeral Components

Indications for Use *(Describe)*

The Equinoxe Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total shoulder arthroplasty are as follows:
- Osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head
- Pathologies where arthrodesis or re sectional 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)
- To restore mobility from previous procedures (e.g. previous fusion)

In the USA, the Equinoxe Stemless Shoulder is only indicated for total shoulder arthroplasty.

The Equinoxe Stemless Shoulder humeral components are indicated for press-fit, uncemented use.

When used in total shoulder arthroplasty, the Equinoxe Stemless Shoulder System is intended to be used with the cemented Equinoxe glenoid components.

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.

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Exactech® Equinoxe® Stemless Humeral Components
Traditional 510(k) – 510(k) Summary

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

Date: July 30, 2019

Contact Person: Zach Sharrah
Manager, Regulatory Affairs

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

Proprietary Name: Exactech® Equinoxe® Stemless Humeral Components

Common Name: Shoulder Prosthesis

Classification Name: Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem with No Diaphyseal Incursion, Semi-Constrained, 21 CFR 888.3660, Class II, Product Code PKC

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Exactech Equinoxe Stemless Shoulder (K173388)

Reference Devices

- Tornier Simpliciti Shoulder System (K143552)
- Equinoxe Humeral Heads (K042021, K140063)

Device Description

The Equinoxe Stemless Humeral Components are intended to be used with Exactech Equinoxe Stemless Humeral Heads and the Equinoxe glenoid components for use in Total Shoulder Arthroplasty. The Exactech glenoid components are indicated for cemented use. The proposed Equinoxe Stemless Humeral Components are additively manufactured from Ti-6Al-4V and have porous regions. The Equinoxe Stemless Humeral Components are available in in three sizes, with lengths between 17mm and 24mm.

Exactech® Equinoxe® Stemless Humeral Components
Traditional 510(k) – 510(k) Summary

Indications for Use
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Clinical indications for anatomic total shoulder arthroplasty are as follows:

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- Pathologies where arthrodesis or re sectional 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)
- To restore mobility from previous procedures (e.g. previous fusion)

In the USA, the Equinoxe Stemless Shoulder is only indicated for total shoulder arthroplasty.

The Equinoxe Stemless Shoulder humeral components are indicated for press-fit, uncemented use.

When used in total shoulder arthroplasty, the Equinoxe Stemless Shoulder System is intended to be used with the cemented Equinoxe glenoid components.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech Equinoxe Stemless Shoulder components and the predicate devices have similar indications for use.
- **Materials/Surface Finish/Coatings.** The proposed Exactech Equinoxe Stemless Humeral Components and the predicate devices are composed of the similar biocompatible substrate materials, and the same or similar surface finish for permanent implants.
- **Design Features.** The proposed Exactech Equinoxe Stemless Shoulder components and the predicate devices have similar design features.
- **Dimensions.** The proposed Exactech Equinoxe Stemless Shoulder components and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Exactech Equinoxe Stemless Shoulder components and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Equinoxe Stemless Shoulder components and the predicate devices conform to recognized performance standards for total shoulder replacement devices.

Exactech® Equinoxe® Stemless Humeral Components
Traditional 510(k) – 510(k) Summary

Non-Clinical Testing
The following engineering analyses were performed to demonstrate that the Exactech Equinoxe Stemless Shoulder perform as intended and are substantially equivalent to the identified predicate devices:

- Fatigue Testing
- Axial Pull Out Testing
- Torque out Testing
- Taper Disengagement Testing
- Porous Structure Characterization

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Equinoxe Stemless 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
Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Exactech Equinoxe Stemless Shoulder demonstrates substantial equivalence to the referenced predicate devices.