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

August 20, 2019

Re: K191561
Trade/Device Name: Exactech® Equinoxe® Humeral Augmented Trays
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: June 11, 2019
Received: June 13, 2019

Dear Shing Jen Tai:

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,

FOR Vesa Vuniqi
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)*
K191561

Device Name
Exactech® Equinoxe® Humeral Augmented Trays

Indications for Use *(Describe)*

The Equinoxe Humeral Augmented Tray is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in skeletally mature individuals with an intact medial calcar for whom the rotator cuff is irreparable or grossly deficient, a functional deltoid muscle is present, and proximal humeral bone loss is present in cases of:

- 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 arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate humeral stem fixation can be achieved)
- Displaced three- and four-part upper humeral fractures
- Failed ORIF requiring rTSA with an absent or deficient greater tuberosity
- Revision of failed previous reconstructions when distal anchorage is required
- Treatment of unplanned proximal bone loss during a revision
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Humeral Augmented Tray can be used in either primary or revision arthroplasty procedures.

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® Humeral Augmented Trays
Traditional 510(k) - 510(k) Summary

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

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

FDA Establishment Number 1038671

Contact Person: Shing Jen Tai, PhD
Principal Regulatory Affairs Specialist

Date: August 8, 2019

Proprietary Name: Exactech® Equinoxe® Humeral Augmented Trays

Common Name: Reverse shoulder prosthesis

Regulation Number: 21 CFR 888.3650
21 CFR 888.3660

Classification Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Shoulder joint metal/polymer semi-constrained cemented prosthesis

Device Class: Class II

Product Code: PHX, KWT, KWS

Classification Panel: Orthopedic

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K063569	Equinoxe Reverse Shoulder System (Humeral Adapter Trays)	Exactech, Inc
K082702	Equinoxe Reverse Shoulder System + 15mm Humeral Adapter Tray	Exactech, Inc

Exactech® Equinoxe® Humeral Augmented Trays
Traditional 510(k) - 510(k) Summary

Information on reference device:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K143659	Equinoxe Humeral Reconstruction Prosthesis	Exactech, Inc

Indications for Use

The Equinoxe Humeral Augmented Tray is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in skeletally mature individuals with an intact medial calcar for whom the rotator cuff is irreparable or grossly deficient, a functional deltoid muscle is present, and proximal humeral bone loss is present in cases of:

- 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 arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate humeral stem fixation can be achieved)
- Displaced three- and four-part upper humeral fractures
- Failed ORIF requiring rTSA with an absent or deficient greater tuberosity
- Revision of failed previous reconstructions when distal anchorage is required
- Treatment of unplanned proximal bone loss during a revision
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Humeral Augmented Tray can be used in either primary or revision arthroplasty procedures.

Device Description

The Exactech Equinoxe Humeral Augmented Trays are intended for use in total shoulder arthroplasty in skeletally mature patients with proximal humeral bone loss. Specifically, Equinoxe Humeral Augmented Trays are used in combination with Equinoxe Reverse Shoulder System components to compensate for proximal humeral bone loss in presence of an intact medial calcar, irreparable or grossly deficient rotator cuff and a functional deltoid muscle. One of the overall goals of the anatomically designed Equinoxe Humeral Augmented Trays is to improve joint mechanics and stability by providing increased deltoid muscle wrapping and adequate soft tissue tensioning in patients with proximal humeral bone loss.

The Equinoxe Humeral Augmented Trays are consisted of a humeral tray component, a modular extension (augment) and a universal locking screw for use in primary and revision cases. To accommodate patients' various anatomical needs, Equinoxe Humeral Augmented Trays are anatomically designed with two offsets/thicknesses and multiple lateralizations of left and right humeral trays and left and right modular extensions. Per

surgeon evaluation, the modular extension secured with a locking screw is used to replace greater and more severe proximal humeral bone loss than can be adequately addressed with use of humeral tray component alone. When the modular extension is used, the locking screw must be used to secure it to the humeral tray component. All three components of the Equinoxe Humeral Augmented Trays are manufactured from Titanium Alloy (Ti-6Al-4V).

Non-Clinical Testing

The following mechanical testing, engineering analysis, and cadaveric evaluation were performed to demonstrate that the Exactech Equinoxe Humeral Augmented Trays perform as intended and are substantially equivalent to the identified predicate Equinoxe Humeral Adapter Trays previously cleared in K063569 and K082702:

- Fatigue strength testing under worst-case lateral loading
- Fatigue strength testing under worst-case medial loading
- Range of Motion Analysis
- Cadaveric evaluation

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Equinoxe Humeral Augmented Trays 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 non-clinical testing including mechanical testing, engineering analysis and cadaveric evaluation demonstrate the proposed Exactech Equinoxe Humeral Augmented Trays are substantially equivalent to the previously cleared Humeral Adapter Trays in the Exactech Equinoxe Reverse Shoulder System.