September 25, 2023

Exactech, Inc
Valdimir Talley
Regulatory Specialist
2320 NW 66th Ct.
Gainesville, Florida 32653

Re: K223933
Trade/Device Name: Exactech® Equinoxe® PHx® Fracture System; Exactech® EPIC Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 25, 2023
Received: August 25, 2023

Dear Mr. Talley:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223933

Device Name
Exactech® Equinoxe® PHx® Fracture System;
Exactech® EPIC Screws

Indications for Use *(Describe)*
Exactech® Equinoxe® PHx® Fracture System:

The Exactech® Equinoxe® PHx® Fracture System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the proximal humerus. Specific clinical indications for ORIF are as follows: fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Exactech® EPIC Screws:

The 3.5mm diameter Exactech® EPIC Screws of the Epic Extremity Plate System (cleared under K153340) are also intended for use with the Exactech® Equinoxe® PHx® Fracture System for Open Reduction Internal Fixation procedures of the proximal humerus.

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® PHx® Fracture System with Exactech® EPIC Screws
Traditional 510(k) – 510(k) Summary

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

Phone: (352) 327-4824
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact Person: Valdimir Talley III
Regulatory Affairs Specialist

Date: September 22, 2023

Proprietary Name: Exactech® Equinoxe® PHx® Fracture System
Exactech® EPIC Screws

Common Name: Proximal Humeral Fracture Plate System

Regulation Number and Classification Names: 21 CFR 888.3030 (Primary) – Single/multiple component metallic bone fixation appliances and accessories.
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener.

Device Class: Class II

Product Codes: HRS – Plate, Fixation, Bone
HWC – Screw, Fixation, Bone

Classification Panel: Orthopedic

Table 1. Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Predicate Designation	510(k) Number	Trade or Proprietary Model Name	Manufacturer
Primary	K093978	Exactech® Equinoxe® Proximal Humerus Fracture Plate System	Exactech, Inc
Additional	K153340	Epic Extremity Plate System	Exactech, Inc
Additional	K111352	Talon™ DistalFix™ Proximal Femoral Nail	Orthopedic Designs North America, Inc. (ODi)
Additional	K051412	Humeral Head Plate with Angular Stability	Implants for Trauma Surgery (ITS)
Additional	K133668	AFT™ GTF System	Shoulder Options

Exactech® Equinoxe® PHx® Fracture System with Exactech® EPIC Screws
Traditional 510(k) – 510(k) Summary

Device Description

The Exactech® Equinoxe® PHx® Fracture System is a set of plate and screw components for use in Open Reduction Internal Fixation (ORIF) applications for fractures of the proximal humerus. The Exactech® Equinoxe® PHx® Fracture System includes various sizes and styles of fracture plates and fixation screws and is to be used with the 3.5mm diameter Exactech® EPIC locking and non-locking style screws (cleared under K153340). The Exactech® Equinoxe® PHx® Fracture System with the Exactech® EPIC Screws are intended to be used for internal fixation of fractures, fracture dislocations, non-unions, and osteotomies of the proximal humerus.

The Exactech® EPIC Screws were previously cleared with the Epic Extremity Plate System with an indication for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. This is an indication change only for the 3.5mm EPIC locking and non-locking screws.

Indications for Use

Exactech® Equinoxe® PHx® Fracture System:

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Exactech® EPIC Screws:

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Summary of Device Characteristics Comparison

The rationale for substantial equivalence is based on consideration of the following device use, design characteristics and performance requirements:

Indications for Use

- The proposed and predicate devices have the same indications for use.

Materials

- The proposed and predicate devices are composed of similar, well-established, biocompatible materials.

Design Features

- The proposed and predicate devices have the same or similar design features.

Sterilization

- The proposed and predicate devices are provided non-sterile for single use, with the exception of the Exac-Loc™ screw.
- The Exac-Loc™ Screw is provided sterile for single use.

Performance Requirements

- The proposed and predicate devices conform to recognized performance standards for multi-component bone screw and plate fixation systems.

Non-Clinical Testing

The following non-clinical testing and engineering analyses were performed to demonstrate that the Exactech® Equinoxe® PHx® Fracture System and the 3.5mm diameter Exactech EPIC Screws, as intended, are substantially equivalent to the identified predicate devices:

- Single cycle bend testing (ASTM F382)
- Cyclic fatigue bend testing (ASTM F382)
- Bend fatigue resistance testing of Exac-Loc™ Screw anchor feature (ASTM F384)
- Bone screw performance testing (ASTM F543)
- Biocompatibility
- Bacterial endotoxins

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® PHx® Fracture System and the 3.5mm diameter Exactech EPIC Screws demonstrate substantial equivalence to the predicate devices.