Exactech, Inc.
Kenneth Maxwell
Sr. Regulatory Affairs Specialist
2320 NW 66th Ct.
Gainesville, Florida 32653

March 4, 2022

Re: K212356
Trade/Device Name: Exactech® Equinoxe® Laser Cage Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: February 1, 2022
Received: February 2, 2022

Dear Kenneth Maxwell:

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 Lixin Liu, Ph.D.
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: 06/30/2023
See PRA Statement on last page.

510(k) Number *(if known)*
K212356

Device Name
Exactech® Equinoxe® Laser Cage Glenoid

Indications for Use *(Describe)*

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems, and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		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 fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
√	√		To restore mobility from previous procedures (e.g. previous fusion)

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.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

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® Laser Cage Glenoid
Traditional 510(k) - 510(k) Summary

Company	Exactech, Inc. 2320 NW 66th Court Gainesville, FL 32653
Contact Person	Kenneth C. Maxwell II Senior Regulatory Affairs Specialist Phone: (352) 377-1140 Fax: (352) 378-2617
Date	4 March 2022
Proprietary Name	Exactech® Equinoxe® Laser Cage Glenoid
Common Name	Shoulder prosthesis, glenoid component
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis (Class II per 21 CFR §888.3660)
Product Code	KWS
Classification Panel	Orthopedic

DEVICE DESCRIPTION

The Equinoxe Laser Cage Glenoids are intended to be used with Exactech Equinoxe Humeral Head components in Total Shoulder Arthroplasty. The Laser Cage Glenoids are composed of an Ultra High Molecular Weight Polyethylene (UHMWPE) body molded onto Ti-6Al-4V peripheral pegs and a central cage. The central cage and peripheral pegs of the implant are additively manufactured using direct metal printing (DMP) technology. The Laser Cage Glenoids are available in four sizes and four augment angle options.

INDICATIONS FOR USE

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems, and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		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

Exactech® Equinoxe® Laser Cage Glenoid
Traditional 510(k) - 510(k) Summary

√	√		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 fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
√	√		To restore mobility from previous procedures (e.g. previous fusion)

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.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

TECHNOLOGICAL CHARACTERISTICS

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

- **Indications for Use.** The proposed Laser Cage Glenoids and the predicate devices have identical indications for use.
- **Materials.** The proposed Laser Cage Glenoids and the predicate devices are composed of identical biocompatible materials.
- **Design Features.** The proposed Laser Cage Glenoids and the predicate devices have the same design features.
- **Dimensions.** The proposed Laser Cage Glenoids and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Laser Cage Glenoids and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Laser Cage Glenoids and the predicate devices conform to the same recognized performance standards.

Exactech® Equinoxe® Laser Cage Glenoid
Traditional 510(k) - 510(k) Summary

LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

Primary Predicate:

510k Number	Trade or Proprietary or Model Name	Manufacturer
K113309	Equinoxe® Cage Glenoid	Exactech, Inc.

Additional Predicates:

510k Number	Trade or Proprietary or Model Name	Manufacturer
K121220	Equinoxe 12° Posterior Augment Pegged Glenoid	Exactech, Inc.
K111379	Equinoxe 16° Posterior Augment Pegged Glenoid	Exactech, Inc.

REFERENCE DEVICE

510k Number	Trade or Proprietary or Model Name	Manufacturer
K192097	Equinoxe® Stemless Humeral Components	Exactech, Inc.

NON-CLINICAL TESTING

The Equinoxe Laser Cage Glenoid has been tested in the following test modes:

- Porous Structure Characterization
- Glenoid Fixation
- Peg Shear Resistance
- Peg Pull-Off
- Peg Bending Fatigue

Bacterial endotoxin testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Laser Cage Glenoid meets 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, biocompatibility of the proposed devices, and results of non-clinical testing, it was concluded the Equinoxe Laser Cage Glenoid demonstrates substantially equivalence to the predicate devices.