



August 1, 2025

Exactech Inc.  
Liz Howell  
Principal Regulatory Specialist  
2320 NW 66th Court  
Gainesville, Florida 32653

Re: K243448

Trade/Device Name: Equinoxe® Shoulder System  
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, PAO  
Dated: June 17, 2025  
Received: June 17, 2025

Dear Liz Howell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Joseph P. Russell**

Digitally signed by Joseph P.  
Russell -S

-S

Date: 2025.08.01 08:54:18 -04'00'

for: Farzana Sharmin, PhD

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

**Indications for Use**

510(k) Number (if known)  
K243448

Device Name  
Equinoxe® Shoulder System

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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## Equinoxe® Shoulder System 510(k) Summary

**Applicant:** Exactech®, Inc.  
2320 NW 66<sup>th</sup> Court  
Gainesville FL, 32653

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

**Applicant Contact:** Liz Howell  
Senior Manager, Regulatory Affairs  
Telephone: (352) 377-1140  
Fax: (352) 378-2617

**Date:** July 31, 2025

**Device Trade Name:** Equinoxe® Shoulder System

**Common Name:** Shoulder Prosthesis, Reverse Configuration

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

**Regulation Number:** 888.3660, 888.3650

**Product Code:** PHX, KWS, KWT, PAO

### Legally Marketed Predicate Devices:

Predicate Number	Predicate Trade Name	Product Code
K223833	Exactech® Equinoxe® Reverse Humeral Liners and Humeral Adapter Trays	PHX

### Reference Devices:

Reference Number	Reference Trade Name	Product Code
K232002	Vantage® Total Ankle System	HSN

### Device Description Summary

The proposed Equinoxe Activit-E Reverse Humeral Liners are humeral liners intended to be used in reverse total shoulder arthroplasty (rTSA) as a part of the Equinoxe® Shoulder System. The proposed devices are constructed of highly crosslinked UHMWPE containing vitamin E referred to as Activit-E. There are no

## Equinoxe® Shoulder System 510(k) Summary

proposed geometric or compatibility changes as compared to the predicate humeral liner devices cleared in K223833.

### Intended Use/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 of 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

## **Equinoxe® Shoulder System 510(k) Summary**

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.

### **Indications for Use Comparison**

The subject and the predicate devices have the same indications for use.

### **Technological Comparison**

The proposed and predicate devices have the same intended use and basic fundamental scientific technology. The technological difference between the predicate and proposed devices is the material. The proposed devices are constructed of highly crosslinked UHMWPE containing vitamin E referred to as Activit-E, whereas the predicate devices are constructed of conventional UHMWPE. There are no proposed geometric or compatibility changes as compared to the predicate humeral liner devices. The rationale for substantial equivalence of the proposed to the predicate cleared devices is based on consideration of the following aspects of the devices:

- The proposed and predicate devices are composed of similar biocompatible materials.
- The proposed and predicate devices have the same design features.
- The proposed and predicate devices are provided sterile for single use only.
- The proposed and predicate devices conform to recognized performance standards for shoulder replacement devices.

### **Non-Clinical and/or Clinical Tests Summary & Conclusions**

The following non-clinical testing and engineering analyses were performed to demonstrate that the Equinoxe® Shoulder System performs as intended and is substantially equivalent to the identified predicate devices:

- Humeral Liner-Tray fatigue testing
- Humeral Liner-Tray disassembly testing
- Humeral Liner Mode I wear testing
- Post-wear testing particle analysis per ASTM F1877-05:2010

**Equinox® Shoulder System**  
**510(k) Summary**

- Biocompatibility per ISO 10993-1:2018
- Bacterial endotoxins per USP <161>, USP <85> and ANSI/AAMI ST72

The differences in material do not change the intended use, safety, or performance requirements of the proposed devices, nor do they adversely affect their safety or effectiveness. This conclusion is based on consideration of the preclinical testing and analysis including humeral liner-tray fatigue and disassembly testing, humeral liner wear testing and particle analysis, and biocompatibility assessment completed to establish substantial equivalence of the proposed devices to the predicate devices.