December 1, 2025

Exactech, Inc.
Kiel Johnson
Sr Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K250713
Trade/Device Name: Equinoxe® Humeral Reconstruction Prosthesis; Equinoxe® Stemless Shoulder Implants
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, PHX, HSD, PKC
Dated: October 31, 2025
Received: October 31, 2025

Dear Kiel Johnson:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250713 ?

Please provide the device trade name(s). ?

Equinoxe® Humeral Reconstruction Prosthesis;
Equinoxe® Stemless Shoulder Implants

Please provide your Indications for Use below. ?

Humeral Reconstruction Prosthesis
The Equinoxe® Humeral Reconstruction Prosthesis System is intended for use in hemi or total shoulder arthroplasty where proximal humeral resection is deemed necessary in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Correction of functional deformity
- Treatment of acute or chronic fracture with humeral head involvement, which are unmanageable using other treatment
- Traumatic arthritis
- Oncology applications including bone loss due to tumor resection.
- Significant humeral resection which are unmanageable using other treatment methods

The Equinoxe® Humeral Reconstruction Prosthesis System can be used in either primary or revision arthroplasty procedures.
The Equinoxe® Humeral Reconstruction Prosthesis System is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in which significant resection of the proximal humerus is necessary, the rotator cuff is irreplaceable and grossly deficient, and a functional deltoid muscle is present. In the USA, the Equinoxe® Humeral Reconstruction Prosthesis System is not indicated for use with the Equinoxe Reverse Shoulder System components in oncology applications.
The Equinoxe® Humeral Reconstruction Prosthesis Distal Stems are for cemented use only, while the HA coated Equinoxe® Humeral Reconstruction Prosthesis Distal Stem Collars are only for uncemented, press-fit use.

Stemless Shoulder
The Equinoxe® Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total 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 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).
- To restore mobility from previous procedures (e.g. previous fusion).

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

The Equinoxe® Stemless Shoulder System is intended to be used with the cemented Equinoxe® glenoid components.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) #: K250713

510(k) Summary

Prepared on: 2025-12-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Exactech, Inc.
Applicant Address	2320 N.W. 66th Court Gainesville FL 32653 United States
Applicant Contact Telephone	352-377-1140
Applicant Contact	Mr. Kiel Johnson
Applicant Contact Email	kiel.johnson@exac.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Equinoxe® Humeral Reconstruction Prosthesis; Equinoxe® Stemless Shoulder Implants
Common Name	Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented
Classification Name	Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulation Number	888.3650
Product Code(s)	KWT, KWS, PHX, HSD, PKC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143659	Equinoxe® Mega Prosthesis	KWT
K162903	Equinoxe® Humeral Reconstruction Prosthesis Extra-Small Proximal Bodies	KWT
K173388	Exactech Equinoxe Stemless Shoulder Implant System	PKC
K192097	Exactech Equinoxe Stemless Shoulder Implant System	PKC

Device Description Summary

21 CFR 807.92(a)(4)

Humeral Reconstruction Prosthesis
The Exactech Equinoxe Humeral Reconstruction Prosthesis is designed to replace both the articulating surface of the shoulder (humeral head) as well as resected humerus. The modular design of the system allows for a surgeon to construct the middle and proximal segments of the prosthesis in various lengths in order to match the length of resected bone and maintain the natural arm length of the patient.

The prosthesis is manufactured from Ti-6Al-4V and has both Titanium Plasma Spray and HA coated regions. The proximal bodies are available in five sizes (Extra-Small, Small, Medium, Large, Extra-Large) and two lengths (+0mm, +12.5mm). The middle segments are available in 3 lengths (25mm, 50mm, 75mm) with one diameter. The distal stems are available in 3 lengths (80mm, 120mm, 200mm) and 6 diameters (6mm, 7mm, 8mm, 9mm, 11mm, 13mm). The distal stem collars are available in 17 diameters (17.5mm-33.5mm, 1mm increments). The distal stem collars are intended for press-fit fixation. The proximal bodies and middle segments have suture throughholes to facilitate soft tissue attachment.

Stemless Shoulder

The Equinoxe Stemless Shoulder is intended to be used with Exactech glenoid components for use in Total Shoulder Arthroplasty. The Equinoxe Stemless Shoulder includes humeral components and humeral heads. The Equinoxe Stemless Humeral Components are additively manufactured from Titanium Alloy and have porous regions. The Stemles Humeral Heads are made from Cobalt Chrome Alloy. The Equinoxe Stemless Humeral Components are available in 3 sizes, and the Stemless Humeral Heads are available in available in 12 sizes, with diameters between 36mm and 53mm and two height options (Extra Short, Short).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Humeral Reconstruction Prosthesis
The Equinoxe® Humeral Reconstruction Prosthesis System is intended for use in hemi or total shoulder arthroplasty where proximal humeral resection is deemed necessary in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
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- Significant humeral resection which are unmanageable using other treatment methods

The Equinoxe® Humeral Reconstruction Prosthesis System can be used in either primary or revision arthroplasty procedures.
The Equinoxe® Humeral Reconstruction Prosthesis System is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in which significant resection of the proximal humerus is necessary, the rotator cuff is irreplaceable and grossly deficient, and a functional deltoid muscle is present.
In the USA, the Equinoxe® Humeral Reconstruction Prosthesis System is not indicated for use with the Equinoxe Reverse Shoulder System components in oncology applications.
The Equinoxe® Humeral Reconstruction Prosthesis Distal Stems are for cemented use only, while the HA coated Equinoxe® Humeral Reconstruction Prosthesis Distal Stem Collars are only for uncemented, press-fit use.

Stemless Shoulder
The Equinoxe® Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total 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 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).
- To restore mobility from previous procedures (e.g. previous fusion).

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

The Equinoxe® Stemless Shoulder System is intended to be used with the cemented Equinoxe® glenoid components.

Indications for Use Comparison

21 CFR 807.92(a)(5)

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

Technological Comparison

21 CFR 807.92(a)(6)

The proposed and predicate devices have the same intended use and scientific technology. The difference between the proposed and predicate devices is the addition of MR conditional labeling. 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 the same 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 21 CFR 807.92(b)

The following non-clinical testing and engineering analyses were performed in accordance with ASTM F2503 to characterize the compatibility of Equinoxe® Humeral Reconstruction Prosthesis and Equinoxe® Stemless Shoulder Implants in the MR environment:
• Displacement Testing per ASTM F2052
• Magnetically induced torque per ASTM F2213
• MR image artifact per ASTM F2119
• RF-induced heating per ASTM F2182

There is no clinical testing included this submission.

Results of the non-clinical testing and evaluations that were conducted to establish MR safety considerations support a conclusion of substantial equivalence with the predicate device.