



June 26, 2025

Exactech, Inc  
Valdimir Talley  
Senior Regulatory Affairs Specialist  
2320 NW 66th Court  
Gainesville, Florida 32653

Re: K243275

Trade/Device Name: Equinoxe® Scapula Fracture System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: HRS

Dated: May 28, 2025

Received: May 28, 2025

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 (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.  
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

## Indications for Use

Submission Number (if known)

K243275

Device Name

Equinoxe® Scapula Fracture System

Indications for Use (Describe)

Equinoxe® Scapula Fracture System

The Exactech® Equinoxe® Scapula Fracture System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the scapula. Specific clinical indications for ORIF are as follows: Levy Type I, IIA, and IIB fractures, fracture dislocations, osteotomies, and non-unions of the acromion and scapular spine.

The 3.5mm diameter and 2.7mm diameter Exactech® EPIC Screws of the Epic Extremity Plate System (cleared under K153340) are also intended for use with the Exactech® Equinoxe® Scapula Fracture System for Open Reduction Internal Fixation procedures of the scapula.

The Straight Plates of the EPIC Fracture Plate System (cleared under K172441) are also intended for use with the Exactech® Equinoxe® Scapula Fracture System for Open Reduction Internal Fixation procedures of the scapula.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Exactech, Inc
Applicant Address	2320 NW 66th Court Gainesville FL 32653 United States
Applicant Contact Telephone	2174337871
Applicant Contact	Mr. Valdimir Talley
Applicant Contact Email	valdimir.talley@exac.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Equinoxe® Scapula Fracture System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051083	Acumed Scapula Congruent Bone Plate System	HRS

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Exactech® Equinoxe® Scapula Fracture System with EPIC Screws and Straight Plates is a set of plate and screw components for use in Open Reduction Internal Fixation (ORIF) applications for fractures of the acromion and scapular spine. The Exactech® Equinoxe® Scapula Fracture System includes a range of sizes and options of scapula fracture plates and screws to accommodate varying patient anatomy and needs. Previously cleared components to be used with the Exactech® Equinoxe® Scapula Fracture System include the Exactech® EPIC Locking Screws, EPIC Non-Locking Screws, and EPIC Straight Plates. All components work together in various configurations to address scapular ORIF procedures.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Equinoxe® Scapula Fracture System  
The Exactech® Equinoxe® Scapula Fracture System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the scapula. Specific clinical indications for ORIF are as follows: Levy Type I, IIA, and IIB fractures, fracture dislocations, osteotomies, and non-unions of the acromion and scapular spine.

The 3.5mm diameter and 2.7mm diameter Exactech® EPIC Screws of the Epic Extremity Plate System (cleared under K153340) are also intended for use with the Exactech® Equinoxe® Scapula Fracture System for Open Reduction Internal Fixation procedures of the scapula.

The Straight Plates of the EPIC Fracture Plate System (cleared under K172441) are also intended for use with the Exactech® Equinoxe® Scapula Fracture System for Open Reduction Internal Fixation procedures of the scapula.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject and predicate device systems have similar indications for use. The subject device indications adds "non-unions" to the list of clinical indications, as they are commonly included within the clinical indications for Open Reduction Internal Fixation (ORIF) procedures.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The proposed devices have the same intended use and basic fundamental scientific technology. The rationale for substantial equivalence of the proposed and predicate systems is based on consideration of the following:

- The proposed and predicate devices have similar indications for use.
- The proposed and predicate devices are composed of the same biocompatible material.
- The proposed and predicate devices utilize the same or similar features to achieve fracture fixation.
- The proposed and predicate devices are provided non-sterile for single use.
- The proposed devices conform to recognized guidances and performance standards for multi-component bone screw and plate fixation systems.

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

[21 CFR 807.92\(b\)](#)

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

- Cross-sectional and finite element analysis for worst-case sample selection
- Clinically relevant cycled bend testing
- Corrosion assessment per ASTM F897
- Screw Testing per ASTM F543
- Biocompatibility per ISO 10993-1:2018

Clinical data is not applicable.

The differences in geometry do not change the intended use or performance requirements of the proposed devices. This conclusion is based on consideration of the pre-clinical testing and analysis including bending fatigue testing, screw mechanical performance testing, corrosion assessment, and biocompatibility assessment completed that establish substantial equivalence of the proposed devices to the predicate devices.