

K243275 Equinoxe® Scapula Fracture SystemJun 26, 2025
253 days to decisionK243275 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k243275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 16, 2024
Decision date	Jun 26, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	Valdimir Talley
510(k) history	186 submissions · 174 cleared · 1986-2026

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