

K250713 Equinoxe® Humeral Reconstruction ProsthesisDec 1, 2025
266 days to decisionK250713 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k250713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Mar 10, 2025
Decision date	Dec 1, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Equinoxe® Stemless Shoulder Implants

APPLICANT

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

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