

**K143659 Equinoxe Mega Prosthesis**Apr 9, 2015  
107 days to decisionK143659 · Product code: **KWT** · Orthopedic  
Source: <https://www.510kdatabase.net/k143659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Dec 23, 2014
Decision date	Apr 9, 2015
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	Thomas McNamara
Website	<a href="https://www.exac.com/">https://www.exac.com/</a>
510(k) history	186 submissions · 174 cleared · 1986-2026

Exactech, Inc. operates with a manufacturing facility in Gainesville, US. The company does not offer direct sales or distribution in the United States. Product inquiries and safety concerns are handled through designated company contacts. Exactech has submitted FDA 510(k) applications, resulting in cleared devices. The company's regulatory activity spans from 1986 to 2026, demonstrating sustained engagement with FDA clearance processes. Orthopedic devices represent the dominant focus of the company's portfolio, accounting for approximately 99% of submissions. Recent FDA 5...

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