

**K162903 Exactech Equinox Humeral Reconstruction  
Prosthesis Extra-Small Proximal Bodies**Feb 27, 2017  
133 days to decisionK162903 · Product code: **KWT** · Orthopedic  
Source: <https://www.510kdatabase.net/k162903/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Oct 17, 2016
Decision date	Feb 27, 2017
Days to decision	133 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162903/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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