

**K191561 Exactech Equinox Humeral Augmented Trays**Aug 20, 2019  
68 days to decisionK191561 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k191561/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jun 13, 2019
Decision date	Aug 20, 2019
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	Shing Jen Tai
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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