

**K193098 Exactech® Equinoxe® Reverse Shoulder  
Glenospheres**Feb 20, 2020  
105 days to decisionK193098 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k193098/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 7, 2019
Decision date	Feb 20, 2020
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	Zach Sharrah
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...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k193098/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026