

**K073688 EQUINOXE REVERSE SHOULDER SYSTEM  
FRACTURE HUMERAL ADAPTER TRAY AND LOCKING SCREW**Feb 29, 2008  
63 days to decisionK073688 · Product code: PHX · Orthopedic  
Source: <https://www.510kdatabase.net/k073688/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 28, 2007
Decision date	Feb 29, 2008
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	GRAHAM CUTHBERT
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/k073688/> 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 19, 2026