

K063569 EQUINOXE REVERSE SHOULDER SYSTEMFeb 23, 2007
86 days to decisionK063569 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k063569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 29, 2006
Decision date	Feb 23, 2007
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	AMNON TALMOR
Website	https://www.exac.com/
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...
