FDA 510(k) Premarket Notification

K101909 EXACTECH EQUINOXE, PLATFORM FRACTURE STEM

CLEARED

Aug 2, 2010
25 days to decision

K101909 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k101909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 8, 2010
Decision date	Aug 2, 2010
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	GRAHAM L CUTHBERT
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...