CLEARED

Mar 6, 2017
199 days to decision

K162325 Exactech Equinoxe Reverse Shoulder Locking Cap, Exactech Equinoxe Reverse Shoulder Compression Screws, Exactech Equinoxe Reverse Shoulder Glenosphere Locking Screw

K162325 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k162325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 19, 2016
Decision date	Mar 6, 2017
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	Zach Sharrah
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162325/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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