FDA 510(k) Premarket Notification

CLEARED

K023646 EXATECH ACUMATCH INTEGRATED HIP SYSTEM C-SERIES CEMENTED FEMORAL STEM

Nov 13, 2002
14 days to decision

K023646 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k023646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Oct 30, 2002
Decision date	Nov 13, 2002
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	Lisa Simpson
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...