FDA 510(k) Premarket Notification

CLEARED

K011218 ACUMATCH L-SERIES CEMENTED FEMORAL STEM, MODEL SIZE 1

May 16, 2001
26 days to decision

K011218 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k011218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Apr 20, 2001
Decision date	May 16, 2001
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	GARY J MILLER
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...