FDA 510(k) Premarket Notification

CLEARED

K001335 ACUMATCH L-SERIES CEMENTED FEMORAL STEM, MODEL L-SERIES CEMENTED

May 18, 2000
21 days to decision

K001335 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k001335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Apr 27, 2000
Decision date	May 18, 2000
Days to decision	21 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...