FDA 510(k) Premarket Notification

K013211 MODIFICATION TO: ACUMATCH L-SERIES BIPOLAR ENDOPROSTHESIS

CLEARED

Dec 5, 2001
70 days to decision

K013211 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k013211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Sep 26, 2001
Decision date	Dec 5, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	ROBERT PAXSON
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...