

K905370 EXACTECH BIPOLAR HIP PROSTHESISFeb 27, 1991
90 days to decisionK905370 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k905370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 29, 1990
Decision date	Feb 27, 1991
Days to decision	90 days
Third-party review	No

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	WILLIAM PETTY
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...