FDA 510(k) Premarket Notification

CLEARED

K935773 EXACTECH POROUS COATED POSTERIOR STABILIZED FEMORAL COMPONENT

Dec 9, 1994
371 days to decision

K935773 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k935773/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 3, 1993
Decision date	Dec 9, 1994
Days to decision	371 days
Third-party review	No

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	TIM SEESE
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...