

**K954208 OPTETRAK CONSTRAINED CONDYLAR KNEE FOR
CEMENTED USE ONLY**Feb 26, 1996
172 days to decisionK954208 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k954208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 7, 1995
Decision date	Feb 26, 1996
Days to decision	172 days
Third-party review	No

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	MARTHA C 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...