

K934253 EXACTECH ALL POLY ACETABULAR CUPApr 29, 1994
241 days to decisionK934253 · Product code: **JDZ** · Orthopedic
Source: <https://www.510kdatabase.net/k934253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Cement, For Clinical Use (JDZ)
Date received	Aug 31, 1993
Decision date	Apr 29, 1994
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	TIMOTHY J 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...
