

K143576 Exactech AmbassadorFeb 27, 2015
72 days to decisionK143576 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k143576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 17, 2014
Decision date	Feb 27, 2015
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	DAWN DAVISSON
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...
