FDA 510(k) Premarket Notification

K063685 OPTECURE

CLEARED

Jun 7, 2007
177 days to decision

K063685 · Product code: **MBP** · Orthopedic
Source: https://www.510kdatabase.net/k063685/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Osteoinduction (w/o Human Growth Factor) (MBP)
Date received	Dec 12, 2006
Decision date	Jun 7, 2007
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary
Other names	OPTECURE + CCC

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	MARITZA ELIAS
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...