

**K031430 CEMEX SYSTEM FAST**May 22, 2003  
16 days to decisionK031430 · Product code: **LOD** · Orthopedic  
Source: <https://www.510kdatabase.net/k031430/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Cement (LOD)
Date received	May 6, 2003
Decision date	May 22, 2003
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	GARY J MILLER
Website	<a href="https://www.exac.com/">https://www.exac.com/</a>
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...

---