

**K083392 NOVATION 12/14 CEMENTED FEMORAL STEMS**Dec 17, 2008  
30 days to decisionK083392 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k083392/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Nov 17, 2008
Decision date	Dec 17, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	GRAHAM L CUTHBERT
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...