

**K032964 EXACTECH 12/14 ALUMINA FEMORAL HEAD**Nov 13, 2003  
51 days to decisionK032964 · Product code: LPH · Orthopedic  
Source: <https://www.510kdatabase.net/k032964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Sep 23, 2003
Decision date	Nov 13, 2003
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary
Other names	EXACTECH ACUMATCH M-SERIES 12/14 NECK SEGMENTS

**APPLICANT**

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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...

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