

**K914574 EXACTECH CERAMIC FEMORAL HEAD COMPONENT**Jan 13, 1992  
90 days to decisionK914574 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k914574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Oct 15, 1991
Decision date	Jan 13, 1992
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	TIM SEESE
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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