

K103012 EXACTECH BIOLOXDELTA / BIOLOX FEMORAL HEADS, 28MM OD, 32MM OD, 36MM OD, EXACTECH BIOLOX OPTION ADAPTERS/FEMORAL HEADSNov 10, 2010
29 days to decisionK103012 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k103012/>**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	Oct 12, 2010
Decision date	Nov 10, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	LINDY KNISELY
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...