

K221323 Exactech® Alteon® Short Tapered WedgeMay 19, 2023
378 days to decisionK221323 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k221323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	May 6, 2022
Decision date	May 19, 2023
Days to decision	378 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	Valdimir Talley
510(k) history	186 submissions · 174 cleared · 1986-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221323/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026