

**K213580 Adapter Sleeve for BIOLOX® OPTION Femoral Head,
+10.5mm head length**Dec 3, 2021
23 days to decisionK213580 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k213580/>**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 10, 2021
Decision date	Dec 3, 2021
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Total Joint Othopedics, Inc.
Location	Salt Lake City, UT, US
Contact	Chris Weaber
510(k) history	8 submissions · 8 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213580/> 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 26, 2026