

K953690 CLS STEM (MODIFICATION)Jun 7, 1996
312 days to decisionK953690 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k953690/>**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	Jul 31, 1995
Decision date	Jun 7, 1996
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intermedics Orthopedics
Location	Mchenry, IL, US
Contact	BARRY J HASSETT
510(k) history	108 submissions · 82 cleared · 1982-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953690/> 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 21, 2026