

K971409 OSTEONICS ALUMINA C-TAPER HEADJul 9, 1997
84 days to decisionK971409 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k971409/>**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	Apr 16, 1997
Decision date	Jul 9, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteonics Corp.
Location	Mchenry, IL, US
Contact	KATE SUTTON
510(k) history	178 submissions · 136 cleared · 1980-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971409/> 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