

K981302 SMC 28MM CERAMIC FEMORAL HEADSJun 25, 1998
77 days to decisionK981302 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k981302/>**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 9, 1998
Decision date	Jun 25, 1998
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Signal Medical Corp.
Location	Port Huron, MI, US
Contact	LOUIS A SERAFIN, JR.
510(k) history	9 submissions · 9 cleared · 1997-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981302/> 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 18, 2026