

**K970490 PROFORM GENERAL APPLICATION CEMENTED
FEMORAL COMPONENT**May 2, 1997
81 days to decisionK970490 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k970490/>**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	Feb 10, 1997
Decision date	May 2, 1997
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Stelkast Company
Location	Pittsburgh, PA, US
Contact	DONALD A STEVENS
510(k) history	40 submissions · 37 cleared · 1994-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970490/>, 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