

K941612 F-230 POROUS FEMORAL HIP STEM (CEMENTLESS)Jul 6, 1995
458 days to decisionK941612 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k941612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Apr 4, 1994
Decision date	Jul 6, 1995
Days to decision	458 days
Third-party review	No

APPLICANT

Company	Implex Corp.
Location	Allendale, NJ, US
Contact	JAMES E MALAYTER
510(k) history	65 submissions · 61 cleared · 1993-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941612/>; 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 14, 2026