

K964882 IMPLEX REPLACEMENT ACETABULAR CUP INSERTMar 13, 1997
98 days to decisionK964882 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k964882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Dec 5, 1996
Decision date	Mar 13, 1997
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

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/k964882/> 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