

K001759 HEDROCEL REVISION CUP, MODEL 02-2YY-ZZZZAug 24, 2000
76 days to decisionK001759 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k001759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jun 9, 2000
Decision date	Aug 24, 2000
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001759/> 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