

K972928 KERBOULL CROSSNov 3, 1997
87 days to decisionK972928 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k972928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Aug 8, 1997
Decision date	Nov 3, 1997
Days to decision	87 days
Third-party review	No

APPLICANT

Company	Howmedica, Inc.
Location	Rutherford, NJ, US
Contact	FRANK MAAS
510(k) history	36 submissions · 29 cleared · 1994-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972928/>; 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 21, 2026