

K940328 PRIME CEMENTED HIP SYSTEMApr 7, 1995
438 days to decisionK940328 · Product code: **JDI** · Orthopedic
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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jan 24, 1994
Decision date	Apr 7, 1995
Days to decision	438 days
Third-party review	No

APPLICANT

Company	Orthopaedic Innovations, Inc.
Location	Minneapolis, MN, US
Contact	NICHOLAS A GUSTILO
510(k) history	8 submissions · 7 cleared · 1995-2002

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