

K913812 OMNIFIT/OMNIFLEX/ODC/OMNIFIT-HA HIP STEM SERIES

Nov 22, 1991
88 days to decision

K913812 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k913812/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Aug 26, 1991
Decision date	Nov 22, 1991
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteonics Corp.
Location	Mchenry, IL, US
Contact	ROBERT A KOCH
510(k) history	178 submissions · 136 cleared · 1980-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k913812/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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