FDA 510(k) Premarket Notification

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

CLEARED

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