FDA 510(k) Premarket Notification

K882812 OMNIFIT ACETABULAR SHELL CEMENT SPACER SYSTEM

CLEARED

Aug 8, 1988
32 days to decision

K882812 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k882812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jul 7, 1988
Decision date	Aug 8, 1988
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Osteonics Corp.**
Location	Mchenry, IL, US
Contact	DENNIS H CRANE
510(k) history	178 submissions · 136 cleared · 1980-2000

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k882812/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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