

K972460 OSTEONICS OMNIFIT-C CEMENTED HIP STEM (LINE EXTENSION)Sep 25, 1997
86 days to decisionK972460 · Product code: JDI · Orthopedic
Source: <https://www.510kdatabase.net/k972460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jul 1, 1997
Decision date	Sep 25, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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