

K984227 OMEGA II MODULAR TOTAL HIP SYSTEMApr 8, 1999
134 days to decisionK984227 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k984227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Nov 25, 1998
Decision date	Apr 8, 1999
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Osteoimplant Technology, Inc.
Location	Hunt Valley, MD, US
Contact	SAM SON
510(k) history	21 submissions · 20 cleared · 1996-2005

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