

**K000817 OMEGA II MODULAR TOTAL HIP SYSTEM**Jun 8, 2000  
87 days to decisionK000817 · Product code: **JDI** · Orthopedic  
Source: <https://www.510kdatabase.net/k000817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Mar 13, 2000
Decision date	Jun 8, 2000
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000817/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026