

**K951291 OSTEONICS RESTORATION MONOLITHIC HIP STEM**Aug 9, 1995  
156 days to decisionK951291 · Product code: **MEH** · Orthopedic  
Source: <https://www.510kdatabase.net/k951291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Mar 6, 1995
Decision date	Aug 9, 1995
Days to decision	156 days
Third-party review	No

**APPLICANT**

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Company	<b>Osteonics Corp.</b>
Location	Mchenry, IL, US
Contact	ROBERT A KOCH
510(k) history	178 submissions · 136 cleared · 1980-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951291/>, 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 21, 2026