

**K090897 TRITANIUM NON-MODULAR SHELL & X3 ALL-POLY  
INSERT**Oct 23, 2009  
205 days to decisionK090897 · Product code: **LPH** · Orthopedic  
Source: <https://www.510kdatabase.net/k090897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Apr 1, 2009
Decision date	Oct 23, 2009
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	AVITAL MERL-MARGULIES
510(k) history	288 submissions · 288 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090897/>; 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 15, 2026