

**K091166 IMRX**Sep 2, 2009  
133 days to decisionK091166 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k091166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 22, 2009
Decision date	Sep 2, 2009
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imris, Inc.</b>
Location	Rockville, MD, US
Contact	THOMAS M TSAKERIS
510(k) history	14 submissions · 14 cleared · 2006-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091166/> 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 17, 2026