

**K173749 AMRA Profiler**Dec 6, 2018  
363 days to decisionK173749 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k173749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Dec 8, 2017
Decision date	Dec 6, 2018
Days to decision	363 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Amra Medical AB</b>
Location	Linkoping, SE
Contact	Janne West
510(k) history	2 submissions · 2 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173749/> 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 26, 2026