

**K253648 Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades**Feb 23, 2026  
95 days to decisionK253648 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k253648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 20, 2025
Decision date	Feb 23, 2026
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems Nederland B.V.</b>
Location	Best, NL
Contact	Younkyung Oh
510(k) history	103 submissions · 102 cleared · 2005-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253648/> 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 13, 2026