

**K251808 Achieva**Jul 11, 2025  
29 days to decisionK251808 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k251808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 12, 2025
Decision date	Jul 11, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Intera; Ingenia 1.5T; Ingenia 3.0T; Ingenia 1.5T CX; Ingenia 3.0T CX; Ingenia Elition S; Ingenia Elition X; Ingenia Ambition S; Ingenia Ambition X; and MR 5300 MR Systems

**APPLICANT**

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

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