

**K223458 Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition,
MR 5300 and MR 7700 MR Systems**Apr 6, 2023
141 days to decisionK223458 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k223458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 16, 2022
Decision date	Apr 6, 2023
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederland B.V.
Location	Best, NL
Contact	Ioana Ulea
510(k) history	103 submissions · 102 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223458/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026