

K252838 MAGNETOM SolaDec 19, 2025
105 days to decisionK252838 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k252838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Sep 5, 2025
Decision date	Dec 19, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MAGNETOM Altea; MAGNETOM Sola Fit; MAGNETOM Viato.Mobile; MAGNETOM Vida; MAGNETOM Lumina; MAGNETOM Vida Fit; MAGNETOM Flow.Elite; MAGNETOM Flow.Neo; MAGNETOM Flow.Rise

APPLICANT

Company	Siemens Healthcare GmbH
Location	Erlangen, DE
Contact	Hertle Friederike
510(k) history	30 submissions · 30 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	Siemens Medical Solutions USA, Inc.
Contact	Alina Goodman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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