FDA 510(k) Premarket Notification

CLEARED

K260265 MAGNETOM Flow.Ace

Feb 23, 2026
26 days to decision

K260265 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k260265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jan 28, 2026
Decision date	Feb 23, 2026
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MAGNETOM Flow.Plus

APPLICANT

Company	**Siemens Shenzhen Magnetic Resonance , Ltd.**
Location	Shenzhen, CN
Contact	Li Hai Ting
510(k) history	3 submissions · 3 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**Siemens Medical Solutions USA, Inc.**
Contact	Martin Rajchel

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