FDA 510(k) Premarket Notification

K250436 MAGNETOM Flow.Ace

CLEARED

Jun 16, 2025
122 days to decision

K250436 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k250436/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Feb 14, 2025
Decision date	Jun 16, 2025
Days to decision	122 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	Goodman Alina

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