FDA 510(k) Premarket Notification

K221733 MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit

CLEARED

Sep 13, 2022
90 days to decision

K221733 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k221733/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 15, 2022
Decision date	Sep 13, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	Alina Goodman
510(k) history	778 submissions · 778 cleared · 1980-2026