FDA 510(k) Premarket Notification

K101347 MAGNETOM AERA

CLEARED

Oct 1, 2010
141 days to decision

K101347 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k101347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	May 13, 2010
Decision date	Oct 1, 2010
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary
Other names	MAGNETOM SKYRA

APPLICANT

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