

K163312 MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software

Jan 27, 2017
65 days to decision

K163312 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k163312/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 23, 2016
Decision date	Jan 27, 2017
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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