

**K191050 MAGNETOM Aera and MAGNETOM Skyra with
Software syngo MR E11E with Ischemic Heart Disease (IHD)
Workflow**Jul 12, 2019
84 days to decisionK191050 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k191050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 19, 2019
Decision date	Jul 12, 2019
Days to decision	84 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	Milind Dhamankar
510(k) history	779 submissions · 779 cleared · 1980-2026

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