

K193290 AI-Rad Companion Brain MRJun 17, 2020
203 days to decisionK193290 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k193290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 27, 2019
Decision date	Jun 17, 2020
Days to decision	203 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	Lauren Bentley
510(k) history	779 submissions · 779 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193290/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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