

K213706 AI-Rad Companion Brain MRApr 15, 2022
142 days to decisionK213706 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k213706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 24, 2021
Decision date	Apr 15, 2022
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare GmbH
Location	Erlangen, DE
Contact	Kira Kuzmenchuk
510(k) history	30 submissions · 30 cleared · 2016-2026

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