

K253057 AI-Rad Companion Brain MRJan 22, 2026
122 days to decisionK253057 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253057/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Sep 22, 2025 |
| Decision date | Jan 22, 2026 |
| Days to decision | 122 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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