

K243672 CardIQ SuiteJun 18, 2025
203 days to decisionK243672 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k243672/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Nov 27, 2024 |
| Decision date | Jun 18, 2025 |
| Days to decision | 203 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | GE Medical Systems SCS |
| Location | Buc Cedex, FR |
| Contact | Haddad Mireille |
| 510(k) history | 37 submissions · 37 cleared · 2008-2026 |

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