

K253770 CardIQ Suite

Jul 21, 2026  
237 days to decision

K253770 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k253770/>

SUBMISSION DETAILS

|                       |                                           |
|-----------------------|-------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received         | Nov 26, 2025                              |
| Decision date         | Jul 21, 2026                              |
| Days to decision      | 237 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 | 38 submissions · 38 cleared · 2008-2026 |