

K180225 GSI Viewer with GSI Fat OptionApr 24, 2018
88 days to decisionK180225 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k180225/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Jan 26, 2018 |
| Decision date | Apr 24, 2018 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180225/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026