

K012836 MODIFICATION TO: LIGHTSPEED PLUS MOBILE CT SYSTEM

Sep 7, 2001
15 days to decision

K012836 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k012836/>

SUBMISSION DETAILS

| | |
|-----------------------|-------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Aug 23, 2001 |
| Decision date | Sep 7, 2001 |
| Days to decision | 15 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | GE Medical Systems |
| Location | Milwaukee, WI, US |
| Contact | LARRY A KROGER |
| 510(k) history | 169 submissions · 166 cleared · 1989-2022 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k012836/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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