

K082104 GE LIGHTSPEED RT16 / LIGHTSPEED XTRA V2 CT SYSTEM (AKA GE LIGHTSPEED RT16 / LIGHTSPEED XTRA CT SYSTEM)Sep 2, 2008
39 days to decisionK082104 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k082104/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Jul 25, 2008 |
| Decision date | Sep 2, 2008 |
| Days to decision | 39 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ge Medical Systems, Inc. |
| Location | Milwaukee, WI, US |
| Contact | STEVEN KACHELMEYER |
| 510(k) history | 54 submissions · 54 cleared · 1997-2009 |

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