

K201103 Xeleris V Processing and Review SystemsSep 25, 2020
154 days to decisionK201103 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k201103/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Apr 24, 2020 |
| Decision date | Sep 25, 2020 |
| Days to decision | 154 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ge Healthcare |
| Location | Waukesha, WI, US |
| Contact | Alexandra Lifshits |
| Website | http://www3.gehealthcare.com/en |
| 510(k) history | 168 submissions · 168 cleared · 2004-2026 |

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...
