

**K091658 GE INNOVA SOLID STATE XRAY-IMAGER
FLUOROSCOPIC X-RAY SYSTEM, MODELS INNOVA 4100, 3100,
2100, 3131, 2121**Jun 29, 2009
20 days to decisionK091658 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k091658/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Jun 9, 2009 |
| Decision date | Jun 29, 2009 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ge Healthcare |
| Location | Waukesha, WI, US |
| Contact | ALAN TOTAH |
| 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...