

K151685 GUA60A, GU60A-65Jul 17, 2015
25 days to decisionK151685 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k151685/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Stationary (KPR) |
| Date received | Jun 22, 2015 |
| Decision date | Jul 17, 2015 |
| Days to decision | 25 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Samsung Electronics Co., Ltd. |
| Location | Echo, OR, US |
| Contact | Chulsin Kim |
| Website | http://www.samsung.com |
| 510(k) history | 40 submissions · 39 cleared · 2013-2024 |

Samsung Electronics Co., Ltd. is a South Korean multinational electronics corporation headquartered in Suwon. The company maintains a regulatory presence in the United States through its Echo, US location. Samsung has submitted total applications for FDA 510(k) clearance and received clearances. The company's regulatory focus centers on Radiology devices, which represent 83% of submissions. Samsung's FDA 510(k) clearance history spans from 2013 to 2024, with recent clearances demonstrating continued regulatory activity in medical imaging and cardiovascular monitoring tech...
