

**K123106 DIGITAL DIAGNOSTIC X-RAY SYSTEM MODEL XGEO  
GU60A**Jun 20, 2013  
261 days to decisionK123106 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k123106/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Stationary (KPR)    |
| Date received         | Oct 2, 2012                        |
| Decision date         | Jun 20, 2013                       |
| Days to decision      | 261 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Samsung Electronics Co., Ltd.</b>                        |
| Location       | Echo, OR, US  |
| Contact        | CHARLIE MACK  |
| Website        | <a href="http://www.samsung.com">http://www.samsung.com</a> |
| 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...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k123106/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026