

**K051967 REVOLUTION XR/D DIGITAL RADIOGRAPHIC IMAGING SYSTEM WITH TOMOSYNTHESIS**Aug 9, 2005  
20 days to decisionK051967 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k051967/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 20, 2005
Decision date	Aug 9, 2005
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	JOHN L SCHMIDT
Website	<a href="http://www3.gehealthcare.com/en">http://www3.gehealthcare.com/en</a>
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...

---

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

Device record: <https://www.510kdatabase.net/k051967/> 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 18, 2026