

K052345 ADVANTAGE SIM MDSep 14, 2005
19 days to decisionK052345 · Product code: **KPQ** · Radiology
Source: <https://www.510kdatabase.net/k052345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Simulation, Radiation Therapy (KPQ)
Date received	Aug 26, 2005
Decision date	Sep 14, 2005
Days to decision	19 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	LARRY A KROGER
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...
