FDA 510(k) Premarket Notification

CLEARED

K052412 INNOVA 2100-IQ, INNOVA 3100, INNOVA 3100-IQ, INNOVA 4100, AND INNOVA 4100-IQ

Sep 16, 2005
14 days to decision

K052412 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k052412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 2, 2005
Decision date	Sep 16, 2005
Days to decision	14 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...