FDA 510(k) Premarket Notification

K101166 4D-VIEW 9.1 (4D VIEW PC SOFTWARE) MODEL: H48651SZ

CLEARED

Oct 7, 2010
164 days to decision

K101166 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k101166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 26, 2010
Decision date	Oct 7, 2010
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare**
Location	Waukesha, WI, US
Contact	BRYAN BEHN
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...