FDA 510(k) Premarket Notification

CLEARED

K092271 GE LOGIQ E9 BT2010 DIAGNOSTIC ULTRASOUND SYSTEM, MODEL 5205000-3, 5205000-4

Nov 17, 2009
112 days to decision

K092271 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k092271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 28, 2009
Decision date	Nov 17, 2009
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare**
Location	Waukesha, WI, US
Contact	NICOLE LANDREVILLE
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...