FDA 510(k) Premarket Notification

CLEARED

K152567 Voluson E6, Voluson E8, Voluson E10 Diagnostic Ultrasound System

Nov 6, 2015
58 days to decision

K152567 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k152567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 9, 2015
Decision date	Nov 6, 2015
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare**
Location	Waukesha, WI, US
Contact	Ayesha Pergadia
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k152567/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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