

**K132913 VOLUSON E6 / E8 / E8EXPERT / E8EXPERT LIMITED
EDITION / E10**Nov 8, 2013
52 days to decisionK132913 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k132913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 17, 2013
Decision date	Nov 8, 2013
Days to decision	52 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132913/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026