

K131514 GE VIVID E9 DIAGNOSTIC ULTRASOUND IMAGING SYSTEM

Jul 12, 2013
45 days to decision

K131514 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k131514/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 28, 2013
Decision date	Jul 12, 2013
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Vingmed Ultrasound AS
Location	Horten, NO
Contact	BRYAN BEHN
510(k) history	10 submissions · 10 cleared · 2009-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131514/> 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 16, 2026