

K101149 GE VIVID E9 DIAGNOSTIC ULTRASOUND IMAGING SYSTEM

Oct 13, 2010
173 days to decision

K101149 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k101149/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 23, 2010
Decision date	Oct 13, 2010
Days to decision	173 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

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Device record: <https://www.510kdatabase.net/k101149/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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