

K152758 Venue 50Nov 18, 2015
55 days to decisionK152758 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k152758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 24, 2015
Decision date	Nov 18, 2015
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound and Primary Care Diagnostics
Location	Wauwatosa, WI, US
Contact	TRACEY ORTIZ
510(k) history	64 submissions · 64 cleared · 2015-2026

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