

K243628 Vivid T9/Vivid T8Feb 11, 2025
78 days to decisionK243628 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k243628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 25, 2024
Decision date	Feb 11, 2025
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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