

K202658 Vivid E80/ Vivid E90/ Vivid E95Mar 5, 2021
172 days to decisionK202658 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k202658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 14, 2020
Decision date	Mar 5, 2021
Days to decision	172 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	Tracey Ortiz
510(k) history	64 submissions · 64 cleared · 2015-2026

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