

K251169 Vivid PioneerJul 10, 2025
86 days to decisionK251169 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k251169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 15, 2025
Decision date	Jul 10, 2025
Days to decision	86 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	Lee Bush
510(k) history	64 submissions · 64 cleared · 2015-2026

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