

K251322 VenueJul 25, 2025
87 days to decisionK251322 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k251322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 29, 2025
Decision date	Jul 25, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Venue Go; Venue Fit; Venue Sprint

APPLICANT

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

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