

K240111 VenueJun 10, 2024
146 days to decisionK240111 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k240111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 16, 2024
Decision date	Jun 10, 2024
Days to decision	146 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	Karin Shimoni
510(k) history	64 submissions · 64 cleared · 2015-2026

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