

**K240053 Venue Go**Jun 10, 2024  
154 days to decisionK240053 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k240053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 8, 2024
Decision date	Jun 10, 2024
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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