

**K234106 Venue Fit**Jun 10, 2024  
167 days to decisionK234106 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k234106/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 26, 2023
Decision date	Jun 10, 2024
Days to decision	167 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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