

K203137 Venue FitDec 29, 2020
70 days to decisionK203137 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k203137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 20, 2020
Decision date	Dec 29, 2020
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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