

K183362 Venue GOJan 28, 2019
55 days to decisionK183362 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k183362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 4, 2018
Decision date	Jan 28, 2019
Days to decision	55 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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