

K220800 Venue GoJun 21, 2022
95 days to decisionK220800 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k220800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 18, 2022
Decision date	Jun 21, 2022
Days to decision	95 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	Lee Bush
510(k) history	64 submissions · 64 cleared · 2015-2026

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