

K202132 VenueNov 13, 2020
105 days to decisionK202132 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k202132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 31, 2020
Decision date	Nov 13, 2020
Days to decision	105 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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