

K220619 Vivid S60N, Vivid S70NJul 15, 2022
134 days to decisionK220619 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k220619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 3, 2022
Decision date	Jul 15, 2022
Days to decision	134 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	Tracey Ortiz
510(k) history	64 submissions · 64 cleared · 2015-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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