

K180599 VenueMay 2, 2018
56 days to decisionK180599 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k180599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 7, 2018
Decision date	May 2, 2018
Days to decision	56 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026