

K253370 LOGIQ TotusJan 8, 2026
100 days to decisionK253370 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k253370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 30, 2025
Decision date	Jan 8, 2026
Days to decision	100 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253370/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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