

K261835 LOGIQ Focus

Jul 30, 2026
58 days to decision

K261835 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k261835/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 2, 2026
Decision date	Jul 30, 2026
Days to decision	58 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	66 submissions · 66 cleared · 2015-2026