

K252557 Lumify Diagnostic Ultrasound SystemDec 22, 2025
131 days to decisionK252557 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k252557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 13, 2025
Decision date	Dec 22, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Ultrasound, LLC
Location	Bothell, WA, US
Contact	Gina Quiram
510(k) history	20 submissions · 20 cleared · 2022-2026

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