

K251455 EPIQ Series Diagnostic Ultrasound SystemJul 24, 2025
73 days to decisionK251455 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k251455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 12, 2025
Decision date	Jul 24, 2025
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affiniti Series Diagnostic Ultrasound System

APPLICANT

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

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