

K251651 EPIQ Series Diagnostic Ultrasound SystemOct 9, 2025
133 days to decisionK251651 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k251651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 29, 2025
Decision date	Oct 9, 2025
Days to decision	133 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	Swetha Paritala
510(k) history	20 submissions · 20 cleared · 2022-2026

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