

**K243794 EPIQ Series Diagnostic Ultrasound System**Feb 6, 2025  
58 days to decisionK243794 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k243794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 10, 2024
Decision date	Feb 6, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affiniti Series Diagnostic Ultrasound System

**APPLICANT**

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Company	<b>Philips Ultrasound, LLC</b>
Location	Bothell, WA, US
Contact	Deval Patel
510(k) history	20 submissions · 20 cleared · 2022-2026

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