

K250886 EPIQ Series Diagnostic Ultrasound Systems

Jun 18, 2025
85 days to decision

K250886 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k250886/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 25, 2025
Decision date	Jun 18, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affiniti Series Diagnostic Ultrasound Systems

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k250886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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