

K253595 EPIQ Series Diagnostic Ultrasound System, Affiniti Series Diagnostic Ultrasound SystemMar 27, 2026
129 days to decisionK253595 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k253595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 18, 2025
Decision date	Mar 27, 2026
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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