

K261211 Philips EPIQ Series Diagnostic Ultrasound System

Jul 27, 2026
104 days to decision

K261211 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k261211/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 14, 2026
Decision date	Jul 27, 2026
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary
Other names	Philips Affiniti Series Diagnostic Ultrasound System

APPLICANT

Company	Philips Ultrasound, LLC
Location	Bothell, WA, US
Contact	Colin Jacob
510(k) history	24 submissions · 24 cleared · 2022-2026