FDA 510(k) Premarket Notification

K260123 EPIQ Series Diagnostic Ultrasound System

CLEARED

May 27, 2026
132 days to decision

K260123 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k260123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 15, 2026
Decision date	May 27, 2026
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Ultrasound, LLC**
Location	Bothell, WA, US
Contact	Aditi Chaubal
510(k) history	23 submissions · 23 cleared · 2022-2026