

K233545 EPIQ Series Diagnostic Ultrasound SystemNov 30, 2023
27 days to decisionK233545 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k233545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 3, 2023
Decision date	Nov 30, 2023
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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