

**K233788 EPIQ Series Diagnostic Ultrasound System, Affiniti Series Diagnostic Ultrasound System**Feb 13, 2024  
77 days to decisionK233788 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k233788/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 28, 2023
Decision date	Feb 13, 2024
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233788/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026