

**K242519 Lumify Diagnostic Ultrasound System**May 15, 2025  
265 days to decisionK242519 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k242519/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 23, 2024
Decision date	May 15, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Philips Ultrasound</b>
Location	Andover, MA, US
Contact	Sudipta Chakrabarti
510(k) history	5 submissions · 5 cleared · 2004-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242519/> 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 13, 2026