

**K192226 Lumify Diagnostic Ultrasound System**Sep 6, 2019  
21 days to decisionK192226 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192226/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 16, 2019
Decision date	Sep 6, 2019
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Philips Health Care</b>
Location	Bothell, WA, US
Contact	Paul Elias
510(k) history	20 submissions · 20 cleared · 2011-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192226/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 15, 2026