

**K162549 Lumify Ultrasound System**Oct 3, 2016  
20 days to decisionK162549 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k162549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 13, 2016
Decision date	Oct 3, 2016
Days to decision	20 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162549/> 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 June 15, 2026