

**K170761 LIGHTSonic BUBM**Apr 13, 2018  
396 days to decisionK170761 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k170761/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 13, 2017
Decision date	Apr 13, 2018
Days to decision	396 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lightmed USA, Inc.</b>
Location	San Clemente, CA, US
Contact	Katrina Hsu
510(k) history	2 submissions · 2 cleared · 2018-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170761/> 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 28, 2026