FDA 510(k) Premarket Notification

K170761 LIGHTSonic BUBM

CLEARED

Apr 13, 2018
396 days to decision

K170761 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k170761/

SUBMISSION DETAILS

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

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