

**K182213 QT Ultrasound Breast Scanner - 1**Sep 14, 2018  
30 days to decisionK182213 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k182213/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 15, 2018
Decision date	Sep 14, 2018
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Qt Ultrasound, LLC</b>
Location	Novato, CA, US
Contact	Mark W. Lenox
510(k) history	3 submissions · 3 cleared · 2017-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182213/> 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