

K192573 Dolphin Medical Imaging USB Ultrasound SystemNov 19, 2019
62 days to decisionK192573 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k192573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 18, 2019
Decision date	Nov 19, 2019
Days to decision	62 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dolphin Medical Imaging, LLC
Location	Folsom, CA, US
Contact	Brian S. Heaney
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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