

K192253 SonicEye Dual-Array Ultrasound SystemFeb 25, 2020
189 days to decisionK192253 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k192253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 20, 2019
Decision date	Feb 25, 2020
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonivate Medical, Inc.
Location	Portland, OR, US
Contact	Steve Hesler
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192253/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026