

K190039 EchoSure Diagnostic Ultrasound SystemMar 8, 2019
59 days to decisionK190039 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k190039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jan 8, 2019
Decision date	Mar 8, 2019
Days to decision	59 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Sonavex, Inc.
Location	Baltimore, MD, US
Contact	David Narrow
510(k) history	3 submissions · 3 cleared · 2018-2025

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