

K243479 EchoGuide (Version 1)Apr 23, 2025
166 days to decisionK243479 · Product code: **IYO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 8, 2024
Decision date	Apr 23, 2025
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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