

K233977 VelacurSep 4, 2024
261 days to decisionK233977 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k233977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 18, 2023
Decision date	Sep 4, 2024
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonic Incytes
Location	Vancouver, CA
Contact	Tinuade Orimalade
510(k) history	4 submissions · 4 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Z&B Enterprises, Inc.
Contact	Rhona Shanker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233977/> 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 May 14, 2026