

K232459 VelacurSep 12, 2023
28 days to decisionK232459 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k232459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 15, 2023
Decision date	Sep 12, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonic Incytes
Location	Vancouver, CA
Contact	Barry Allen
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

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