

K251728 Velacur One (LI-1100)Jun 26, 2025
21 days to decisionK251728 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k251728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 5, 2025
Decision date	Jun 26, 2025
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonic Incytes Medical Corp
Location	Vancouver, CA
Contact	Tinuade Orimalade
510(k) history	1 submissions · 1 cleared · 2025-2025

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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