

**K223287 Velacur**Apr 20, 2023  
177 days to decisionK223287 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k223287/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 25, 2022
Decision date	Apr 20, 2023
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sonic Incytes</b>
Location	Vancouver, CA
Contact	Barry Allen
510(k) history	4 submissions · 4 cleared · 2020-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Z&amp;B Enterprises, Inc.</b>
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)

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