

K203657 Vu-Path Ultrasound SystemJun 25, 2021
192 days to decisionK203657 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k203657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 15, 2020
Decision date	Jun 25, 2021
Days to decision	192 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Crystalline Medical
Location	Fremont, CA, US
Contact	Ivan Ma
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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