

**K213436 Clarius Ultrasound Scanner**Nov 15, 2021  
24 days to decisionK213436 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k213436/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 22, 2021
Decision date	Nov 15, 2021
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clarius Mobile Health Corp.</b>
Location	Vancouver, CA
Contact	Agatha Szeliga
510(k) history	12 submissions · 12 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213436/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026