

K253593 Clarius Ejection Fraction AIMar 2, 2026
105 days to decisionK253593 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 17, 2025
Decision date	Mar 2, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

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