

K232257 Clarius Bladder AINov 13, 2023
108 days to decisionK232257 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k232257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 28, 2023
Decision date	Nov 13, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
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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