

K243853 Clarius Prostate AIApr 16, 2025
121 days to decisionK243853 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 16, 2024
Decision date	Apr 16, 2025
Days to decision	121 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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