

**K233358 SCoV-2 Ag Detect Rapid Test**Aug 23, 2024  
329 days to decisionK233358 · Product code: **QVF** · Microbiology  
Source: <https://www.510kdatabase.net/k233358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Simple Point-of-care Device To Directly Detect Sars-cov-2 Viral Targets From Clinical Specimens In Near-patient Settings (QVF)
Date received	Sep 29, 2023
Decision date	Aug 23, 2024
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>InBios International, Inc.</b>
Location	Seattle, WA, US
Contact	Annabel Tsai
510(k) history	7 submissions · 5 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233358/> 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 14, 2026