

K232643 Cue COVID-19 Molecular TestNov 28, 2023
90 days to decisionK232643 · Product code: **QWB** · Microbiology
Source: <https://www.510kdatabase.net/k232643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Molecular Test To Detect Sars-cov-2 From Clinical Specimens (QWB)
Date received	Aug 30, 2023
Decision date	Nov 28, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cue Health, Inc.
Location	San Diego, CA, US
Contact	Sharon Young
510(k) history	2 submissions · 1 cleared · 2023-2023

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