

K233842 iHealth COVID-19 Antigen Rapid TestMay 31, 2024
179 days to decisionK233842 · Product code: **QYT** · Microbiology
Source: <https://www.510kdatabase.net/k233842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Dec 4, 2023
Decision date	May 31, 2024
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ihealth Labs, Inc.
Location	Sunnyvale, CA, US
Contact	Tianyang Liu
510(k) history	4 submissions · 4 cleared · 2024-2025

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