

K231795 QuickVue COVID-19 TestMar 22, 2024
276 days to decisionK231795 · Product code: **QYT** · Microbiology
Source: <https://www.510kdatabase.net/k231795/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Over-the-counter Covid-19 Antigen Test (QYT) |
| Date received | Jun 20, 2023 |
| Decision date | Mar 22, 2024 |
| Days to decision | 276 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Quidel Corporation |
| Location | San Diego, CA, US |
| Contact | Suzanne Thomas |
| 510(k) history | 37 submissions · 35 cleared · 2010-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231795/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026