

K230349 Lyra RSV+hMPV AssayMar 10, 2023
29 days to decisionK230349 · Product code: **OEM** · Microbiology
Source: <https://www.510kdatabase.net/k230349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Human Metapneumovirus (hmpv) Rna Assay System (OEM)
Date received	Feb 9, 2023
Decision date	Mar 10, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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