

K233688 Sofia 2 SARS Antigen+ FIADec 13, 2023
26 days to decisionK233688 · Product code: **QVF** · Microbiology
Source: <https://www.510kdatabase.net/k233688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
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	Nov 17, 2023
Decision date	Dec 13, 2023
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sofia 2 SARS Antigen+ FIA Control Swab Set

APPLICANT

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

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