

K211342 Sofia 2 Campylobacter FIANov 23, 2021
204 days to decisionK211342 · Product code: **LQP** · Microbiology
Source: <https://www.510kdatabase.net/k211342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Campylobacter Spp. (LQP)
Date received	May 3, 2021
Decision date	Nov 23, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211342/> 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