

K254295 Sofia Lyme FIA

Jul 10, 2026
191 days to decision

K254295 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k254295/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 31, 2025
Decision date	Jul 10, 2026
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary
Other names	Sofia 2 Campylobacter FIA

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc. (QuidelOrtho)
Location	San Diego, CA, US
Contact	Xiaoxi Wang
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k254295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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