

K173496 Sofia 2 Lyme FIA, Sofia Lyme Control SetAug 30, 2018
290 days to decisionK173496 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k173496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 13, 2017
Decision date	Aug 30, 2018
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corporation
Location	San Diego, CA, US
Contact	Jennifer S. Rial
510(k) history	37 submissions · 35 cleared · 2010-2024

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