

K163713 Sofia Lyme FIA, Sofia Lyme Control SetOct 20, 2017
294 days to decisionK163713 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k163713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 30, 2016
Decision date	Oct 20, 2017
Days to decision	294 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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