

**K173691 Sofia Lyme FIA, Sofia 2 analyzer, Sofia 2 Installation Pack**Feb 28, 2018  
89 days to decisionK173691 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k173691/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 1, 2017
Decision date	Feb 28, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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