

K113847 BORRELIA BURGENDORFERI IGG BLOT TESTApr 11, 2012
104 days to decisionK113847 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k113847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 29, 2011
Decision date	Apr 11, 2012
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gold Standard Diagnostics
Location	Davis, CA, US
Contact	NAPOLEON MONCE
510(k) history	14 submissions · 14 cleared · 2012-2021

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