

K080012 PLATELIA LYME IGG ASSAYMay 8, 2008
126 days to decisionK080012 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k080012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 3, 2008
Decision date	May 8, 2008
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad
Location	Mchenry, IL, US
Contact	FRAN WHITE
Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017

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