

**K180264 Gold Standard Diagnostics Borrelia burgdorferi
IgG/IgM ELISA Test Kit**May 2, 2018
92 days to decisionK180264 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k180264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 30, 2018
Decision date	May 2, 2018
Days to decision	92 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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