

**K200023 Gold Standard Diagnostics Borrelia burgdorferi IgM
ELISA Test Kit**Apr 6, 2020
91 days to decisionK200023 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k200023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 6, 2020
Decision date	Apr 6, 2020
Days to decision	91 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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