

K203289 Gold Standard Diagnostics Borrelia burgdorferi VlsE-OspC IgG/IgM ELISA Test KitMar 22, 2021
133 days to decisionK203289 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k203289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 9, 2020
Decision date	Mar 22, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	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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