

**K203292 Gold Standard Diagnostics Borrelia burgdorferi
IgG/IgM ELISA Test Kit**Mar 22, 2021
133 days to decisionK203292 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k203292/>**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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026