

K172254 Lyme B. burgdorferi (IgM) MarStripe TestOct 23, 2017
89 days to decisionK172254 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k172254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jul 26, 2017
Decision date	Oct 23, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech
Location	Jamestown, NY, US
Contact	Kevin Lawson
510(k) history	5 submissions · 5 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172254/> 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 31, 2026