

**K163095 Lyme B. burgdorferi (IgG) MarStripe Test**Feb 1, 2017  
89 days to decisionK163095 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k163095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 4, 2016
Decision date	Feb 1, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163095/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 31, 2026