

K033083 BORRELIA BURGENDORFERI IGG/IGM ELISA TEST SYSTEMNov 26, 2003
58 days to decisionK033083 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k033083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 29, 2003
Decision date	Nov 26, 2003
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech USA
Location	Jamestown, NY, US
Contact	Bonnie B DeJoy
510(k) history	11 submissions · 11 cleared · 1999-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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