

**K033070 BORRELIA BURGENDORFERI IGM ELISA TEST SYSTEM**Nov 26, 2003  
58 days to decisionK033070 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k033070/>**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	<b>Trinity Biotech USA</b>
Location	Jamestown, NY, US
Contact	Bonnie B DeJoy
510(k) history	11 submissions · 11 cleared · 1999-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033070/> 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 June 6, 2026