

**K965129 BORRELIA BURGENDORFERI IGM ELISA TEST SYSTEM**Mar 26, 1997  
93 days to decisionK965129 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k965129/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 23, 1996
Decision date	Mar 26, 1997
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Wampole Laboratories</b>
Location	Mchenry, IL, US
Contact	WILLIAM L BOTELER JR.
510(k) history	12 submissions · 12 cleared · 1976-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965129/> 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 29, 2026