

**K965131 BORRELIA BURGENDORFERI IGG/IGM ELISA TEST SYSTEM**

Mar 26, 1997  
93 days to decision

K965131 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k965131/>

**SUBMISSION DETAILS**

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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**

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

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Device record: <https://www.510kdatabase.net/k965131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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