

**K991063 QUALICODE B. BURGDORFERI IGG WESTERN BLOT  
KIT, MODEL DK-C052-024**

Sep 21, 1999  
174 days to decision

K991063 · Product code: LSR · Microbiology  
Source: <https://www.510kdatabase.net/k991063/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 31, 1999
Decision date	Sep 21, 1999
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunetics, Inc.</b>
Location	Cambridge,, MA, US
Contact	ANDREW E LEVIN
510(k) history	4 submissions · 4 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k991063/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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