

**K991062 QUALICODE B. BURGDORFERI IGM WESTERN BLOT
KIT, MODEL DK-C062-024**

Sep 21, 1999
174 days to decision

K991062 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k991062/>

SUBMISSION DETAILS

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

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k991062/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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