

**K980351 BBI-BIOTECH RESEARCH LABORATORIES B.
BURGDORFERI IGM WESTERN BLOT KIT**Mar 5, 1999
400 days to decisionK980351 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k980351/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 29, 1998
Decision date	Mar 5, 1999
Days to decision	400 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Biomedica, Inc.
Location	West Bridgewater, MA, US
Contact	DEBRA A PETIT
510(k) history	12 submissions · 12 cleared · 1997-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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