

**K971007 LYME DISEASE B. BURGDORFERI GENOGROUP 1
WESTERN BLOT IGM (WB0400M)**Jun 1, 1998
439 days to decisionK971007 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k971007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 19, 1997
Decision date	Jun 1, 1998
Days to decision	439 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mri Diagnostics
Location	Cypress, CA, US
Contact	MICHAEL J WAGNER
510(k) history	7 submissions · 7 cleared · 1994-2000

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