

**K901054 BION BORRELIA BURGENDORFERI ANTIGEN
SUBSTRATE SLIDE**Apr 5, 1990
30 days to decisionK901054 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k901054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 6, 1990
Decision date	Apr 5, 1990
Days to decision	30 days
Third-party review	No

APPLICANT

Company	Bion Ent., Ltd.
Location	Mchenry, IL, US
Contact	EDWARD NOWAKOWSKI
510(k) history	14 submissions · 14 cleared · 1980-1993

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