

**K981913 PREVUE(TM) BORRELIA BURGENDORFERI ANTIBODY
DETECTION ASSAY**Feb 12, 1999
256 days to decisionK981913 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k981913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jun 1, 1998
Decision date	Feb 12, 1999
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chembio Diagnostic Systems, Inc.
Location	Medford, NY, US
Contact	RAYMOND DATTWYLER
510(k) history	6 submissions · 6 cleared · 1992-2001

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