

**K983606 IS BORRELIA BURGdorFERI IGM TEST SYSTEM**Dec 16, 1998  
63 days to decisionK983606 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k983606/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Oct 14, 1998
Decision date	Dec 16, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Columbia Bioscience, Inc.</b>
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983606/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026