

**K974809 ACCURUN(TM) 130 BORRELIA BURGdorFERI IGG  
POSITIVE CONTROL**Feb 5, 1998  
44 days to decisionK974809 · Product code: LSR · Microbiology  
Source: <https://www.510kdatabase.net/k974809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 23, 1997
Decision date	Feb 5, 1998
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Biomedica, Inc.</b>
Location	West Bridgewater, MA, US
Contact	PATRICIA E GARRETT
510(k) history	12 submissions · 12 cleared · 1997-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974809/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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