

**K974810 ACCURUN(TM) 132 BORRELIA BURDORFERI IGM
POSITIVE CONTROL**Feb 5, 1998
44 days to decisionK974810 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k974810/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974810/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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