

**K032713 BOSTON BIOMEDICA, INC. BORRELIA BURGdorFERI
IGM AND IGG**

Nov 24, 2003
83 days to decision

K032713 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k032713/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 2, 2003
Decision date	Nov 24, 2003
Days to decision	83 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.net

Device record: <https://www.510kdatabase.net/k032713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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