

**K092693 VIRAMED BIOTECH AG BORRELIA B31 IGG
VIRASTRIPE, MODEL V-BBSGUS**Nov 25, 2009
84 days to decisionK092693 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k092693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 2, 2009
Decision date	Nov 25, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Viramed Biotech AG
Location	Oceanside, CA, US
Contact	BARRY MENEFEE
510(k) history	7 submissions · 7 cleared · 2005-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092693/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026