

**K082329 VIRAMED BIOTECH AG BORRELIA B31 IGM
VIRASTRIPE**Aug 5, 2009
356 days to decisionK082329 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k082329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Aug 14, 2008
Decision date	Aug 5, 2009
Days to decision	356 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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