

**K220016 Viramed Borrelia All-In-One ViraChip Test Kit**Aug 19, 2022  
226 days to decisionK220016 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k220016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 5, 2022
Decision date	Aug 19, 2022
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Viramed Biotech AG</b>
Location	Oceanside, CA, US
Contact	Martin Kintrup
510(k) history	7 submissions · 7 cleared · 2005-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Viralab, Inc.</b>
Contact	Leonard Rollins

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220016/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026