

K051169 BIRAMED BIOTECH BORRELIA B31 IGM VIRABLOTAug 11, 2005
104 days to decisionK051169 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k051169/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reagent, Borrelia Serological Reagent (LSR) |
| Date received | Apr 29, 2005 |
| Decision date | Aug 11, 2005 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Statement |

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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