FDA 510(k) Premarket Notification

K220016 Viramed Borrela All-In-One ViraChip Test Kit

CLEARED

Aug 19, 2022
226 days to decision

K220016 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k220016/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Viralab, Inc.**
Contact	Leonard Rollins

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov