

K183446 BioPlex 2200 Lyme TotalMar 12, 2019
90 days to decisionK183446 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k183446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 12, 2018
Decision date	Mar 12, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories
Location	Hauts-De-Seine, FR
Contact	Arlene Carillo
Website	http://www.bio-rad.com
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...