

K120439 BIOPLEX 2200 EBV IGG AND SYPHILIS IGGMar 14, 2012
30 days to decisionK120439 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k120439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Feb 13, 2012
Decision date	Mar 14, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	Juang Wang
Website	http://www.bio-rad.com
510(k) history	82 submissions · 82 cleared · 1991-2019

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...
