

**K123021 BIOPLEX 2200 EBV IGM KIT**Nov 2, 2012  
36 days to decisionK123021 · Product code: **LJN** · Microbiology  
Source: <https://www.510kdatabase.net/k123021/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm, If, Epstein-barr Virus (LJN)
Date received	Sep 27, 2012
Decision date	Nov 2, 2012
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories</b>
Location	Hauts-De-Seine, FR
Contact	Juang Wang
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
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...

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