

**K111072 BIOPLEX 2200 MMRV IGG IT ON BIOPLEX 2200 MULTI-ANALYTE DETECTION SYSTEM, BIOPLEX 2200 MMRV IGG CALIBRATOR SET, AND BIOPL**Aug 23, 2011  
127 days to decisionK111072 · Product code: **OPL** · Microbiology  
Source: <https://www.510kdatabase.net/k111072/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multiplex Immunoassay For Measles Virus, Mumps Virus, Rubella And Varicella Zoster Virus (OPL)
Date received	Apr 18, 2011
Decision date	Aug 23, 2011
Days to decision	127 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...