

K090409 BIOPLEX 2200 HSV-1 AND HSV-2 IGG ON THE BIOPLEX 2200 MULTI-ANALYTE DETECTION SYSTEMMay 8, 2009
79 days to decisionK090409 · Product code: **MXJ** · Microbiology
Source: <https://www.510kdatabase.net/k090409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	Feb 18, 2009
Decision date	May 8, 2009
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories
Location	Hauts-De-Seine, FR
Contact	DAVID V BHEND
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...

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