

**K082036 LYPHOCHEK TUMOR MARKET PLUS CONTROL  
LEVEL 1, 2 AND 3 AND MINIPAK**Sep 8, 2008  
53 days to decisionK082036 · Product code: JJY · Immunology  
Source: <https://www.510kdatabase.net/k082036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jul 17, 2008
Decision date	Sep 8, 2008
Days to decision	53 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	ELIZABETH PLATT
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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