

**K180577 BioPlex 2200 25-OH Vitamin D Kit**Jun 22, 2018  
109 days to decisionK180577 · Product code: **MRG** · Chemistry  
Source: <https://www.510kdatabase.net/k180577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Mar 5, 2018
Decision date	Jun 22, 2018
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories</b>
Location	Hauts-De-Seine, FR
Contact	Arlene Carillo
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...