

**K112810 MULTI-ANALYTE DETECTION SYSTEMS**Oct 26, 2011  
29 days to decisionK112810 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k112810/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Sep 27, 2011
Decision date	Oct 26, 2011
Days to decision	29 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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