

**K935876 ACCESS SPECIFIC IGE ASSAY**Mar 11, 1994  
92 days to decisionK935876 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k935876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Dec 9, 1993
Decision date	Mar 11, 1994
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories, Inc.</b>
Location	Chaska, MN, US
Contact	JOAN CHRISTENSON
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
510(k) history	82 submissions · 82 cleared · 1991-2019

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...

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