

**K963934 ACCESS TROPONIN I REAGENTS ON THE ACCESS  
IMMUNOASSAY ANALYZER MODEL NUMBERS: 33320, 33325  
AND 33329**Dec 16, 1996  
76 days to decisionK963934 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k963934/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 1, 1996
Decision date	Dec 16, 1996
Days to decision	76 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	JAN OLSEN
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...