

**K042336 METER TRAX TRILEVEL, LOW LEVEL, MID LEVEL,
HIGH LEVEL TRILEVEL MINIPAK**Oct 14, 2004
45 days to decisionK042336 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k042336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Aug 30, 2004
Decision date	Oct 14, 2004
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	MARIA ZEBALLOS
Website	http://www.bio-rad.com
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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