

K142448 VARIANT II TURBO HbA1c Kit - 2.0Mar 24, 2015
203 days to decisionK142448 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k142448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Sep 2, 2014
Decision date	Mar 24, 2015
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	Jackie Buckley
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...
