FDA 510(k) Premarket Notification

CLEARED

K070452 VARIANT II HEMOGLOBIN A1C PROGRAM WITH MODELS 270-2101NU

May 7, 2007
80 days to decision

K070452 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k070452/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 16, 2007
Decision date	May 7, 2007
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	JACKIE H 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...