FDA 510(k) Premarket Notification

K140801 VARIANT II TURBO LINK HEMOGLOBIN A1C PROGRAM/TESTING SYSTEM

CLEARED

Jun 25, 2014
86 days to decision

K140801 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k140801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 31, 2014
Decision date	Jun 25, 2014
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	EBONY MCKINNIES
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...