FDA 510(k) Premarket Notification

CLEARED

K171664 Hemoglobin Variants System on Newborn Hemoglobin System with GDM and HbReview Software

Sep 13, 2017
100 days to decision

K171664 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k171664/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Jun 5, 2017
Decision date	Sep 13, 2017
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	Sweta Patel
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...