FDA 510(k) Premarket Notification

CLEARED

K091303 LIQUICHEK HEMATOLOGY-16 CONTROL LV, MODEL: 295LV

Aug 2, 2010
455 days to decision

K091303 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k091303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	May 4, 2009
Decision date	Aug 2, 2010
Days to decision	455 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories**
Location	Hauts-De-Seine, FR
Contact	SUZANNE S PARSONS
Website	http://www.bio-rad.com
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...