FDA 510(k) Premarket Notification

K050682 LIQUICHEK URINE TOXICOLOGY CONTROL (LEVEL C1)

CLEARED

Apr 29, 2005
44 days to decision

K050682 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k050682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Mar 16, 2005
Decision date	Apr 29, 2005
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	ELIZABETH PLATT
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...