

K130963 LIQUICHEK PEDIATRIC CONTROL, LEVEL 1May 6, 2013
28 days to decisionK130963 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k130963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Apr 8, 2013
Decision date	May 6, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary
Other names	LIQUICHEK PEDIATRIC CONTROL, LEVEL 2; LIQUICHEK PEDIATRIC CONTROL, BILEVEL MINIPAK

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	SUZANNE PARSONS
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...