

K123798 LIQUIDCHEK DIABETES CONTROLJan 9, 2013
30 days to decisionK123798 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k123798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 10, 2012
Decision date	Jan 9, 2013
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	LEVEL 1, LEVEL 2, LEVEL 3, TRILEVEL MINIPAK

APPLICANT

Company	Bio-Rad Laboratories
Location	Hauts-De-Seine, FR
Contact	SUZANNE 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...
