

K163015 Liquichek Tumor Marker Control-Level 1Jan 10, 2017
74 days to decisionK163015 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k163015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 28, 2016
Decision date	Jan 10, 2017
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary
Other names	Liquichek Tumor Marker Control-Level 2; Liquichek Tumor Marker Control-Level 3; Liquichek Tumor Marker Control- Trilevel MiniPak

APPLICANT

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