

**K073080 QUEST DIAGNOSTICS SERUM CHEMISTRY
CONTROL, MODELS 935 AND 945**Jan 24, 2008
85 days to decisionK073080 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k073080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 31, 2007
Decision date	Jan 24, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k073080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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