

K181661 QXDx BCR-ABL %IS Kit for use on the QXDx AutoDG ddPCR SystemFeb 13, 2019
233 days to decisionK181661 · Product code: **OYX** · Medical Genetics
Source: <https://www.510kdatabase.net/k181661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bcr/abl1 Monitoring Test (OYX)
Date received	Jun 25, 2018
Decision date	Feb 13, 2019
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	Steve Lin
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...

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