

K202215 cobas BKV, cobas EBV/BKV Control Kit, cobas Buffer Negative Control KitSep 2, 2020
27 days to decisionK202215 · Product code: **QMI** · Microbiology
Source: <https://www.510kdatabase.net/k202215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Test For The Quantitation Of Bk Virus (bk) Dna (QMI)
Date received	Aug 6, 2020
Decision date	Sep 2, 2020
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Rita Hoady
510(k) history	51 submissions · 48 cleared · 1993-2026

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