

K260021 cobas® BV/CV

Jul 16, 2026
192 days to decision

K260021 · Product code: **PQA** · Microbiology
Source: <https://www.510kdatabase.net/k260021/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vaginitis And Bacterial Vaginosis Nucleic Acid Detection System (PQA)
Date received	Jan 5, 2026
Decision date	Jul 16, 2026
Days to decision	192 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	Nicole Gasser
510(k) history	53 submissions · 50 cleared · 1993-2026