

**K190433 cobas TV/MG for use on cobas 6800/8800 systems,  
cobas TV/MG Positive Control Kit, cobas Buffer Negative  
Control Kit**May 22, 2019  
89 days to decisionK190433 · Product code: **QEP** · Microbiology  
Source: <https://www.510kdatabase.net/k190433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Feb 22, 2019
Decision date	May 22, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Nobuko Nakajima
510(k) history	51 submissions · 48 cleared · 1993-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190433/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026