

K202408 cobas CTNG for use on cobas 6800/8800 systemsJan 21, 2021
153 days to decisionK202408 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k202408/>**SUBMISSION DETAILS**

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	Aug 21, 2020
Decision date	Jan 21, 2021
Days to decision	153 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	Aradhana Karthikeyan
510(k) history	49 submissions · 46 cleared · 1993-2025

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