

K260917 cobas CT/NG for use on the cobas 5800/6800/8800 systems

Jul 8, 2026
111 days to decision

K260917 · Product code: QEP · Microbiology
Source: <https://www.510kdatabase.net/k260917/>

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	Mar 19, 2026
Decision date	Jul 8, 2026
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	cobas TV/MG for use on the cobas 5800/6800/8800 systems

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Ginger Emrich
510(k) history	53 submissions · 50 cleared · 1993-2026