

K173887 cobas CT/NG for use on cobas 6800/8800 systemsMar 21, 2018
90 days to decisionK173887 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k173887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Dec 21, 2017
Decision date	Mar 21, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Nobuko Nakajima
510(k) history	49 submissions · 46 cleared · 1993-2025

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