FDA 510(k) Premarket Notification

K150617 cobas HSV 1 and 2 Test

CLEARED

Jun 1, 2015
83 days to decision

K150617 · Product code: **OQO** · Microbiology
Source: https://www.510kdatabase.net/k150617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Mar 10, 2015
Decision date	Jun 1, 2015
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k150617/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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