

K221007 cobas HCVNov 4, 2022
213 days to decisionK221007 · Product code: **MZP** · Microbiology
Source: <https://www.510kdatabase.net/k221007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Hybridization And/or Nucleic Acid Amplification For Detection Of Hepatitis C Rna,hepatitis C Virus (MZP)
Date received	Apr 5, 2022
Decision date	Nov 4, 2022
Days to decision	213 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	Ashley Malich
510(k) history	49 submissions · 46 cleared · 1993-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221007/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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