

**K243753 cobas liat Bordetella panel nucleic acid test**Nov 20, 2025  
350 days to decisionK243753 · Product code: **OZZ** · Microbiology  
Source: <https://www.510kdatabase.net/k243753/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Dec 5, 2024
Decision date	Nov 20, 2025
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Khushvanreep Singh
510(k) history	49 submissions · 46 cleared · 1993-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243753/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026