

K181029 Solana Bordetella Complete AssayJul 15, 2018
88 days to decisionK181029 · Product code: **OZZ** · Microbiology
Source: <https://www.510kdatabase.net/k181029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Apr 18, 2018
Decision date	Jul 15, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corporation
Location	San Diego, CA, US
Contact	Ronald H. Lollar
510(k) history	37 submissions · 35 cleared · 2010-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181029/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026