

K143206 AmpliVue Bordetella AssayDec 10, 2014
33 days to decisionK143206 · Product code: **OZZ** · Microbiology
Source: <https://www.510kdatabase.net/k143206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Nov 7, 2014
Decision date	Dec 10, 2014
Days to decision	33 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

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