

K131728 QUIDEL MOLECULAR INFLUENZA A + B ASSAYAug 29, 2013
78 days to decisionK131728 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k131728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Jun 12, 2013
Decision date	Aug 29, 2013
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corp.
Location	Washington, DC, US
Contact	Ronald H Lollar
510(k) history	93 submissions · 93 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131728/> 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 June 8, 2026