

K173498 Simplexa Bordetella Direct, Simplexa Bordetella Positive Control PackAug 13, 2018
273 days to decisionK173498 · Product code: **OZZ** · Microbiology
Source: <https://www.510kdatabase.net/k173498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Nov 13, 2017
Decision date	Aug 13, 2018
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diasorin Molecular, LLC
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	13 submissions · 12 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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