

**K183223 Simplexa Bordetella Direct, Simplexa Bordetella Positive Control Pack**Dec 19, 2018  
29 days to decisionK183223 · Product code: **OZZ** · Microbiology  
Source: <https://www.510kdatabase.net/k183223/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Nov 20, 2018
Decision date	Dec 19, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183223/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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