FDA 510(k) Premarket Notification

K163626 ARIES Bordetella Assay

CLEARED

May 2, 2017
131 days to decision

K163626 · Product code: **OZZ** · Microbiology
Source: https://www.510kdatabase.net/k163626/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Dec 22, 2016
Decision date	May 2, 2017
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary
Other names	ARIES Bordetella Assay Protocol File Kit

APPLICANT

Company	**Luminex Corporation**
Location	Austin, TX, US
Contact	Kate Linak
Website	http://www.luminexcorp.com/
510(k) history	14 submissions · 14 cleared · 2015-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k163626/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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