FDA 510(k) Premarket Notification

CLEARED

K161220 ARIES® Flu A/B & RSV Assay

Aug 2, 2016
95 days to decision

K161220 · Product code: **OCC** · Microbiology
Source: https://www.510kdatabase.net/k161220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Apr 29, 2016
Decision date	Aug 2, 2016
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Luminex Corporation**
Location	Austin, TX, US
Contact	WENDY RICKER
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/k161220/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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