

**K091667 XTAG RESPIRATORY VIRAL PANEL, MODELS
I019A0110, I019C011, I019D0112, I019E0113, S019-0116**

Jun 25, 2009
16 days to decision

K091667 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k091667/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 9, 2009
Decision date	Jun 25, 2009
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Luminex Molecular Diagnostics, Inc.
Location	Toronto, Ontario, CA
Contact	GLORIA LEE
510(k) history	26 submissions · 22 cleared · 2008-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k091667/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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