

K193167 NxTAG Respiratory Pathogen Panel, NxTAG Respiratory Pathogen Panel Files, SYNCT Software

Dec 11, 2019
26 days to decision

K193167 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k193167/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Nov 15, 2019
Decision date	Dec 11, 2019
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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