

**K112199 XTAG RESPIRATORY VIRAL PANEL, XTAG DATA
ANALYSIS SOFTWARE (TDAS RVP-1)**Sep 1, 2011
31 days to decisionK112199 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k112199/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Respiratory Virus Panel Nucleic Acid Assay System (OCC) |
| Date received | Aug 1, 2011 |
| Decision date | Sep 1, 2011 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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