

K081483 XTAG RESPIRATORY VIRAL PANELJun 25, 2008
28 days to decisionK081483 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k081483/>**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 | May 28, 2008 |
| Decision date | Jun 25, 2008 |
| Days to decision | 28 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 |

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