

K163336 xTAG Cystic Fibrosis 60 Kit v2, xTAG Data Analysis Software (TDAS) CFTRDec 15, 2016
17 days to decisionK163336 · Product code: **NUA** · Medical Genetics
Source: <https://www.510kdatabase.net/k163336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Nov 28, 2016
Decision date	Dec 15, 2016
Days to decision	17 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.netDevice record: <https://www.510kdatabase.net/k163336/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026