

K163347 xTAG Cystic Fibrosis 39 Kit v2

Dec 15, 2016
17 days to decision

K163347 · Product code: **NUA** · Medical Genetics
Source: <https://www.510kdatabase.net/k163347/>

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	Tina Ip
510(k) history	26 submissions · 22 cleared · 2008-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163347/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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