

K083845 XTAG CF60 KIT V2Dec 11, 2009
352 days to decisionK083845 · Product code: **NUA** · Pathology
Source: <https://www.510kdatabase.net/k083845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Dec 24, 2008
Decision date	Dec 11, 2009
Days to decision	352 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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