

**K083846 XTAG CYSTIC FIBROSIS 39 KIT V2, (CFTR 39 KIT V2),  
MODEL I027C0231, I027D0266, I027E0267**Sep 1, 2009  
251 days to decisionK083846 · Product code: **NUA** · Pathology  
Source: <https://www.510kdatabase.net/k083846/>**SUBMISSION DETAILS**

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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	Sep 1, 2009
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Luminex Molecular Diagnostics, Inc.</b>
Location	Toronto, Ontario, CA
Contact	GLORIA LEE
510(k) history	26 submissions · 22 cleared · 2008-2024

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