

K093420 XTAG CYP2D6 KIT V3, MODEL I030C0300 (96 TESTS/KIT), TDAS CYP2D6 SOFTWARE (2030-0254)Aug 26, 2010
296 days to decisionK093420 · Product code: **NTI** · Chemistry
Source: <https://www.510kdatabase.net/k093420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Nov 3, 2009
Decision date	Aug 26, 2010
Days to decision	296 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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