

K131565 XTAG CYP2C19 KIT V3Sep 11, 2013
104 days to decisionK131565 · Product code: **NTI** · Toxicology
Source: <https://www.510kdatabase.net/k131565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	May 30, 2013
Decision date	Sep 11, 2013
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Luminex Molecular Diagnostics, Inc.
Location	Toronto, Ontario, CA
Contact	Ronald Dunn
510(k) history	26 submissions · 22 cleared · 2008-2024

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