

**K170492 xTAG CYP2D6 Kit v3**Aug 11, 2017  
175 days to decisionK170492 · Product code: **NTI** · Toxicology  
Source: <https://www.510kdatabase.net/k170492/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Feb 17, 2017
Decision date	Aug 11, 2017
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170492/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026