

**K140647 XTAG GASTROINTESTINAL PATHOGEN  
 PANEL(GPP)/XTAG DATA ANALYSIS SOFTWARE FOR  
 GPP(TDAS GPP)**

Oct 24, 2014  
 225 days to decision

K140647 · Product code: **PCH** · Microbiology  
 Source: <https://www.510kdatabase.net/k140647/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Mar 13, 2014
Decision date	Oct 24, 2014
Days to decision	225 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	Tina Ip
510(k) history	26 submissions · 22 cleared · 2008-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k140647/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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