

**K140377 XTAG GASTROINTESTINAL PATHOGEN PANEL
(GPP)/XTAG DATA ANALYSIS SOFTWARE FOR GPP (TDAS
GPP)**Sep 16, 2014
214 days to decisionK140377 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k140377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Feb 14, 2014
Decision date	Sep 16, 2014
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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