

K183023 xTAG Gastrointestinal Pathogen Panel (GPP), xTAG Data Analysis Software (TDAS GPP)Nov 30, 2018
29 days to decisionK183023 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k183023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Nov 1, 2018
Decision date	Nov 30, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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