

K191161 xTAG Gastrointestinal Pathogen Panel (GPP)Nov 12, 2019
195 days to decisionK191161 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k191161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	May 1, 2019
Decision date	Nov 12, 2019
Days to decision	195 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

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