FDA 510(k) Premarket Notification

K252329 QIAstat-Dx Gastrointestinal Panel 2

CLEARED

Oct 22, 2025
89 days to decision

K252329 · Product code: **PCH** · Microbiology
Source: https://www.510kdatabase.net/k252329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jul 25, 2025
Decision date	Oct 22, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	QIAstat-Dx GI Panel 2 Mini B&V; QIAstat-Dx GI Panel 2 Mini B

APPLICANT

Company	**QIAGEN GmbH**
Location	Hilden, DE
Contact	Kristen Kanack
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	**Qiagen**
Contact	Pamela Nge

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov