FDA 510(k) Premarket Notification

K243813 QIAstat-Dx GI Panel 2 Mini B&V

CLEARED

Jan 8, 2025
28 days to decision

K243813 · Product code: **PCH** · Microbiology
Source: https://www.510kdatabase.net/k243813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Dec 11, 2024
Decision date	Jan 8, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Qiagen**
Contact	Colleen Adams

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