FDA 510(k) Premarket Notification

K220062 QIAstat-Dx Gastrointestinal Panel 2

CLEARED

May 31, 2024
872 days to decision

K220062 · Product code: **PCH** · Microbiology
Source: https://www.510kdatabase.net/k220062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jan 10, 2022
Decision date	May 31, 2024
Days to decision	872 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**QIAGEN Manchester, Ltd.**
Contact	Selina Salthouse

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