FDA 510(k) Premarket Notification

CLEARED

K233100 QIAstat-Dx® Respiratory Panel Plus

May 10, 2024
227 days to decision

K233100 · Product code: **QOF** · Microbiology
Source: https://www.510kdatabase.net/k233100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Sep 26, 2023
Decision date	May 10, 2024
Days to decision	227 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	Melissa Mahall

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