FDA 510(k) Premarket Notification

CLEARED

K232377 Healgen Rapid COVID-19 Antigen Test

Apr 19, 2024
255 days to decision

K232377 · Product code: **QVF** · Microbiology
Source: https://www.510kdatabase.net/k232377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Simple Point-of-care Device To Directly Detect Sars-cov-2 Viral Targets From Clinical Specimens In Near-patient Settings (QVF)
Date received	Aug 8, 2023
Decision date	Apr 19, 2024
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Healgen Scientific, LLC**
Location	Houston, TX, US
Contact	Jinjie Hu
Website	https://www.healgen.com
510(k) history	27 submissions · 27 cleared · 2012-2026

Healgen Scientific, LLC is a leading in-vitro diagnostics (IVD) developer and manufacturer based in Houston, Texas. Established in 2007, the company specializes in high-quality diagnostic testing technologies across multiple therapeutic areas. Healgen has achieved FDA 510(k) clearances from total submissions since 2012, with no denied submissions on record. The company's regulatory portfolio is dominated by toxicology devices, including drug screening and fentanyl detection products, alongside offerings in chemistry, microbiology, and infectious disease diagnostics. The l...

REGULATORY CONSULTANT

Consulting firm	**Axteria Biomed Consulting**
Contact	Jinjie Hu

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