FDA 510(k) Premarket Notification

CLEARED

K212623 Healgen Strep A Rapid Test Strip (Throat Swab)

Mar 16, 2022
210 days to decision

K212623 · Product code: **GTY** · Microbiology
Source: https://www.510kdatabase.net/k212623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Aug 18, 2021
Decision date	Mar 16, 2022
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Healgen Scientific, LLC**
Location	Houston, TX, US
Contact	Jianqiu Fang
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	**LSI International, Inc.**
Contact	Joe Shia

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