FDA 510(k) Premarket Notification

K260342 AllTest Strep A Rapid Test

CLEARED

Apr 30, 2026
87 days to decision

K260342 · Product code: **GTY** · Microbiology
Source: https://www.510kdatabase.net/k260342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Feb 2, 2026
Decision date	Apr 30, 2026
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou AllTest Biotech Co., Ltd.**
Location	Hangzhou, CN
Contact	Rosa Wu
510(k) history	14 submissions · 14 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**LSI International, Inc.**
Contact	Jenny Xia

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