FDA 510(k) Premarket Notification

CLEARED

K253318 Clungene RSV Antigen Rapid Test

Jan 30, 2026
122 days to decision

K253318 · Product code: **GQG** · Microbiology
Source: https://www.510kdatabase.net/k253318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Sep 30, 2025
Decision date	Jan 30, 2026
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou Clongene Biotech Co., Ltd.**
Location	Hangzhou, CN
Contact	Frank Zheng
510(k) history	9 submissions · 9 cleared · 2016-2026

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k253318/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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