FDA 510(k) Premarket Notification

CLEARED

K241313 OHC COVID-19 Antigen Self Test

May 30, 2025
386 days to decision

K241313 · Product code: **QYT** · Microbiology
Source: https://www.510kdatabase.net/k241313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	May 9, 2024
Decision date	May 30, 2025
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osang, LLC**
Location	Pasadena, CA, US
Contact	Seungyeob Dan Lee
Website	https://www.osangllc.com/
510(k) history	2 submissions · 2 cleared · 2025-2025

Osang, LLC develops diagnostic testing solutions for healthcare providers, laboratories, and communities worldwide. Established in 1996 and headquartered in Seoul, Korea, the company operates a manufacturing facility in Pasadena, California. Osang specializes in rapid diagnostic kits and molecular systems across multiple therapeutic areas. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Microbiology devices. Both clearances were granted in 2025, reflecting active regulatory engagement. Osang's cleared devices include ...

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Lisa Baumhardt

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