FDA 510(k) Premarket Notification

CLEARED

K243262 QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test

Jan 13, 2025
90 days to decision

K243262 · Product code: **SCA** · Microbiology
Source: https://www.510kdatabase.net/k243262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	Oct 15, 2024
Decision date	Jan 13, 2025
Days to decision	90 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, and 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