FDA 510(k) Premarket Notification

CLEARED

K243274 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (VER 2)

Jul 11, 2025
268 days to decision

K243274 · Product code: **OZE** · Microbiology
Source: https://www.510kdatabase.net/k243274/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Oct 16, 2024
Decision date	Jul 11, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	Influenza A SubTyping Kit (VER 4); Influenza B Genotyping Kit (VER 1.1 and 2); and Influenza A/H5 Subtyping Kit (VER 4)

APPLICANT

Company	**Centers For Disease Control and Prevention**
Location	Mchenry, IL, US
Contact	Marie Kirby
510(k) history	29 submissions · 25 cleared · 1981-2025

Centers For Disease Control and Prevention is the United States federal public health agency under the Department of Health and Human Services. Headquartered in Atlanta, Georgia, the CDC protects public health through disease control and prevention domestically and worldwide. The CDC has received FDA 510(k) clearances from total submissions since 1981. The agency's regulatory portfolio is dominated by Microbiology devices, representing 97% of submissions. Latest clearance activity in 2025 demonstrates continued engagement in FDA regulatory pathways. The CDC's cleared devi...