CLEARED

K130551 CDC HUMAN INFLUENZA VIRUS REAL-TIME RT-PCR DIAGNOSTIC PANEL

May 22, 2013
79 days to decision

K130551 · Product code: **OQW** · Microbiology
Source: https://www.510kdatabase.net/k130551/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Mar 4, 2013
Decision date	May 22, 2013
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Centers For Disease Control and Prevention**
Location	Mchenry, IL, US
Contact	HYE-JOO KIM, PHARM. D.
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...