K080570 CDC HUMAN INFLUENZA VIRUS REAL-TIME RT- PCR DETECTION AND CHARACTERIZATION PANEL

CLEARED

Sep 30, 2008
214 days to decision

K080570 · Product code: **NXD** · Microbiology
Source: https://www.510kdatabase.net/k080570/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification, Novel Influenza A Virus, A/h5 (asian Lineage) Rna (NXD)
Date received	Feb 29, 2008
Decision date	Sep 30, 2008
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Centers For Disease Control and Prevention**
Location	Mchenry, IL, US
Contact	STEPHEN LINDSTROM
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...