

K221658 Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set

Jun 10, 2022
2 days to decisionK221658 · Product code: **PBK** · Microbiology
Source: <https://www.510kdatabase.net/k221658/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-variola Orthopoxvirus Real-time Pcr Primer And Probe Set (PBK)
Date received	Jun 8, 2022
Decision date	Jun 10, 2022
Days to decision	2 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	Julie Villanueva, PhD
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...

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