

K192871 B. anthracis Real-time PCR AssayNov 7, 2019
30 days to decisionK192871 · Product code: **NHT** · Microbiology
Source: <https://www.510kdatabase.net/k192871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Nucleic Acid Amplification, Bacillus Anthracis (NHT)
Date received	Oct 8, 2019
Decision date	Nov 7, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	Yon Yu
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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Device record: <https://www.510kdatabase.net/k192871/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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