

K993633 SYNTHETIC VDRL ANTIGENFeb 23, 2000
119 days to decisionK993633 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k993633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Oct 27, 1999
Decision date	Feb 23, 2000
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	VICTORIA POPE
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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