FDA 510(k) Premarket Notification

K812006 LEGIONELLA DIRECT FLUORESCENT ANTIBODY

CLEARED

Sep 8, 1981
54 days to decision

K812006 · Product code: **LHL** · Microbiology
Source: https://www.510kdatabase.net/k812006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Antibody, Legionella, Direct & Indirect Fluorescent (LHL)
Date received	Jul 16, 1981
Decision date	Sep 8, 1981
Days to decision	54 days
Third-party review	No

APPLICANT

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