

K230451 Aptima® Chlamydia trachomatis AssayNov 16, 2023
268 days to decisionK230451 · Product code: **MKZ** · Microbiology
Source: <https://www.510kdatabase.net/k230451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Feb 21, 2023
Decision date	Nov 16, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	Jon Kukowski
Website	https://www.hologic.com/
510(k) history	115 submissions · 111 cleared · 1987-2025

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...

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