FDA 510(k) Premarket Notification

K243345 Aptima BV Assay

CLEARED

Nov 25, 2024
28 days to decision

K243345 · Product code: **PQA** · Microbiology
Source: https://www.510kdatabase.net/k243345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Vaginitis And Bacterial Vaginosis Nucleic Acid Detection System (PQA)
Date received	Oct 28, 2024
Decision date	Nov 25, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Aptima CV/TV Assay

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Gabriela McCoole
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243345/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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