FDA 510(k) Premarket Notification

K190472 Aptima CV/TV Assay

CLEARED

May 16, 2019
79 days to decision

K190472 · Product code: **PQA** · Microbiology
Source: https://www.510kdatabase.net/k190472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vaginitis And Bacterial Vaginosis Nucleic Acid Detection System (PQA)
Date received	Feb 26, 2019
Decision date	May 16, 2019
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Jeffrey Hergesheimer
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 ...