

K200436 Aptima Combo 2 Assay (Panther) - 250 test kit, Aptima Combo 2 Assay (Tigris) - 250 test kit, Aptima Trichomonas Vaginalis (Panther) - 250 test kit, Aptima Trichomonas Vaginalis (Tigris) - 250 test kitMar 23, 2020
28 days to decisionK200436 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k200436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Feb 24, 2020
Decision date	Mar 23, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	Jill Wyland
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 ...