CLEARED

Jun 3, 2022
120 days to decision

K220321 Aptima Combo 2 Assay (250 test kit) Panther, Aptima Combo 2 Assay (250 test kit) Tigris, Aptima Trichomonas Vaginalis Assay (250 test kit) Panther, Aptima Trichomonas Vaginalis Assay (250 test kit) Tigris

K220321 · Product code: **QEP** · Microbiology
Source: https://www.510kdatabase.net/k220321/

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 3, 2022
Decision date	Jun 3, 2022
Days to decision	120 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 ...