

K162673 Aptima Herpes Simplex Viruses 1 & 2 AssayJun 15, 2017
262 days to decisionK162673 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k162673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Sep 26, 2016
Decision date	Jun 15, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	Ron Domingo
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 ...
