FDA 510(k) Premarket Notification

# K153223 ProParaFlu+ Assay

**CLEARED**

Dec 9, 2015
33 days to decision

K153223 · Product code: **OOU** · Microbiology
Source: https://www.510kdatabase.net/k153223/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Parainfluenza Multiplex Nucleic Acid Assay (OOU) |
| Date received | Nov 6, 2015 |
| Decision date | Dec 9, 2015 |
| Days to decision | 33 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 ...