

K251868 Panther Fusion GI Bacterial AssaySep 25, 2025
99 days to decisionK251868 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k251868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jun 18, 2025
Decision date	Sep 25, 2025
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hologic
Location	Danbury, CT, US
Contact	Patricia Villarreal
Website	http://www.hologic.com
510(k) history	2 submissions · 2 cleared · 2016-2025

Hologic develops innovative medical technologies for women's health, diagnostics, and medical imaging. The company operates globally across 36 countries with approximately 7,000 employees and holds over 4,100 patents. Hologic maintains a manufacturing facility in Danbury, Connecticut. The company has received FDA 510(k) clearances from total submissions since 2016. Recent cleared devices span microbiology and radiology specialties, including molecular diagnostics and imaging accessories. The latest clearance in 2025 confirms active regulatory engagement. Hologic's product...

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Device record: <https://www.510kdatabase.net/k251868/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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