

**K242877 BioCode Gastrointestinal Pathogen Panel (GPP)**Jan 10, 2025  
109 days to decisionK242877 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k242877/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Sep 23, 2024
Decision date	Jan 10, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Applied BioCode, Inc.</b>
Location	Santa Fe Springs, CA, US
Contact	Alex Chang
Website	<a href="https://www.apbiocode.com">https://www.apbiocode.com</a>
510(k) history	5 submissions · 5 cleared · 2018-2026

Applied BioCode, Inc. is an in-vitro diagnostics manufacturer specializing in multiplex testing products. The company designs, develops, and commercializes syndromic panel assays using proprietary Barcoded Magnetic Bead technology. Applied BioCode operates with a manufacturing facility in Santa Fe Springs, California. The company has received FDA 510(k) clearances from total submissions since 2018. All submissions focus on Microbiology devices, reflecting the company's core expertise in pathogen detection. The latest clearance in 2026 demonstrates continued regulatory act...