

K190585 Biocode Gastrointestinal Pathogen Panel (GPP)Jun 5, 2019
91 days to decisionK190585 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k190585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Mar 6, 2019
Decision date	Jun 5, 2019
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied BioCode, Inc.
Location	Santa Fe Springs, CA, US
Contact	Robert Di Tullio
Website	https://www.apbiocode.com
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...