

K181427 BD MAX Enteric Viral Panel, BD MAX InstrumentNov 29, 2018
181 days to decisionK181427 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k181427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jun 1, 2018
Decision date	Nov 29, 2018
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Laura Stewart
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagement...
