

K250358 BD Enteric Bacterial Panel for BD COR System, BD Enteric Bacterial Panel plus for BD COR System, and Enteric Bacterial Panel Diluent for BD COR System

Oct 31, 2025
266 days to decision

K250358 · Product code: **PCI** · Microbiology
Source: <https://www.510kdatabase.net/k250358/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Bacterial Panel Multiplex Nucleic Acid-based Assay System (PCI)
Date received	Feb 7, 2025
Decision date	Oct 31, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Joseph Basore
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...