

**K143648 BD MAX Enteric Parasite Panel, BD MAX Instrument**Aug 25, 2015  
246 days to decisionK143648 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k143648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Dec 22, 2014
Decision date	Aug 25, 2015
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Becton, Dickinson and Company</b>
Location	Franklin Lakes, NJ, US
Contact	PAUL SWIFT
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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...

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