

K150815 BD FACSPresto System, BD FACSPresto CD4/Hb Cartridge, BD FACSPresto CD4/Hb Cartridge KitDec 17, 2015
265 days to decisionK150815 · Product code: **PMG** · Immunology
Source: <https://www.510kdatabase.net/k150815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Multicolor Fluorescent Imaging Cytometric Analysis System (PMG)
Date received	Mar 27, 2015
Decision date	Dec 17, 2015
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Catherine(Katie) Bessette
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...

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