FDA 510(k) Premarket Notification

K260213 BD BACTEC FXI Culture System

CLEARED

May 28, 2026
125 days to decision

K260213 · Product code: **MDB** · Microbiology
Source: https://www.510kdatabase.net/k260213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Blood Culturing (MDB)
Date received	Jan 23, 2026
Decision date	May 28, 2026
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bd Diagnostic Systems**
Location	Sparks, MD, US
Contact	Susan Kircher
510(k) history	6 submissions · 6 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	**Bd Diagnostic Systems**
Contact	Susan Kircher

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: https://www.510kdatabase.net/k260213/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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