

K120994 BD BACTEC Plus PRIME Aerobic/F Culture VialsAug 7, 2012
127 days to decisionK120994 · Product code: **MDB** · Microbiology
Source: <https://www.510kdatabase.net/k120994/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Blood Culturing (MDB) |
| Date received | Apr 2, 2012 |
| Decision date | Aug 7, 2012 |
| Days to decision | 127 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Becton, Dickinson and Company |
| Location | Franklin Lakes, NJ, US |
| Contact | Paul Swift |
| 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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