

K130197 BD PHASEAL CLOSED SYSTEM TRANSFER DEVICE - P55Feb 27, 2013
30 days to decisionK130197 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k130197/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB) |
| Date received | Jan 28, 2013 |
| Decision date | Feb 27, 2013 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Becton, Dickinson and Company |
| Location | Franklin Lakes, NJ, US |
| Contact | JOHN ROBERTS |
| 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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