

## K201099 BD PhaSeal Optima Closed System Drug Transfer Device

Aug 12, 2020  
110 days to decision

K201099 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k201099/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Apr 24, 2020
Decision date	Aug 12, 2020
Days to decision	110 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	Amy Honey
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k201099/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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