

**K250059 BD PhaSeal™ Optima Connecting Set (C83-O)**Sep 12, 2025  
245 days to decisionK250059 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k250059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jan 10, 2025
Decision date	Sep 12, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BD PhaSeal™ Optima Spike Set (C180-O)

**APPLICANT**

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Company	<b>Becton, Dickinson and Company</b>
Location	Franklin Lakes, NJ, US
Contact	Melissa Iwu
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...