

**K241988 ProSeal™ Closed System Bag Access**Oct 23, 2024  
107 days to decisionK241988 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k241988/>**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	Jul 8, 2024
Decision date	Oct 23, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Epic Medical Pte. , Ltd.</b>
Location	Singapore, SG
Contact	Freddie Lee
510(k) history	21 submissions · 21 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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