

**K243976 ZeroClear™ Bag Access (423100)**Jan 22, 2025  
30 days to decisionK243976 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k243976/>**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	Dec 23, 2024
Decision date	Jan 22, 2025
Days to decision	30 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/k243976/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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