

**K241476 ToxiSeal™ Vial Adaptor with External Flip Balloon**Jun 21, 2024  
28 days to decisionK241476 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k241476/>**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	May 24, 2024
Decision date	Jun 21, 2024
Days to decision	28 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/k241476/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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