

**K222929 ToxiSeal Vial Adapter with External Balloon**Jan 11, 2024  
472 days to decisionK222929 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k222929/>**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	Sep 26, 2022
Decision date	Jan 11, 2024
Days to decision	472 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/k222929/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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