

**K241442 eZSURE™ Empty Fluid Container with ProSeal™  
Injection Site**Jun 21, 2024  
30 days to decisionK241442 · Product code: **KPE** · General Hospital  
Source: <https://www.510kdatabase.net/k241442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Container, I.v. (KPE)
Date received	May 22, 2024
Decision date	Jun 21, 2024
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/k241442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026