

K241735 ProSeal™ In Line Pump Set (423850)Oct 10, 2024
115 days to decisionK241735 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k241735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jun 17, 2024
Decision date	Oct 10, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241735/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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