

K251722 ProSeal™ Transfer Injector (421120, 421130, 421140)Dec 5, 2025
184 days to decisionK251722 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k251722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jun 4, 2025
Decision date	Dec 5, 2025
Days to decision	184 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/k251722/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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