

K240171 ProSeal™ Injector Plus (Model no. 421050)Mar 28, 2024
66 days to decisionK240171 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k240171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jan 22, 2024
Decision date	Mar 28, 2024
Days to decision	66 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/k240171/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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