

K192075 ProSeal™ Closed System drug Transfer Device (CSTD)Aug 7, 2020
371 days to decisionK192075 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k192075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Aug 2, 2019
Decision date	Aug 7, 2020
Days to decision	371 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

REGULATORY CONSULTANT

Consulting firm	G&L Scientific, Inc.
Contact	Roshana Ahmed

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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