

K230343 ProSeal™ Closed System Administration SetNov 3, 2023
268 days to decisionK230343 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k230343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 8, 2023
Decision date	Nov 3, 2023
Days to decision	268 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/k230343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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