FDA 510(k) Premarket Notification

K230343 ProSeal™ Closed System Administration Set

CLEARED

Nov 3, 2023
268 days to decision

K230343 · 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