

K251340 ProSeal™ Bag Spike with Additive Port (423370ST, 423370)May 29, 2025
29 days to decisionK251340 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k251340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Apr 30, 2025
Decision date	May 29, 2025
Days to decision	29 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

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