

K242152 SMARTeZ™ Elastomeric Infusion Pump (498111, 498121, 498131, 498141)

Oct 7, 2024
76 days to decision

K242152 · Product code: **MEB** · General Hospital
Source: <https://www.510kdatabase.net/k242152/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Elastomeric (MEB)
Date received	Jul 23, 2024
Decision date	Oct 7, 2024
Days to decision	76 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.net

Device record: <https://www.510kdatabase.net/k242152/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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