

**K250234 SMARTeZ™ Elastomeric Infusion Pump (RS series)**Apr 24, 2026  
452 days to decisionK250234 · Product code: **MEB** · General Hospital  
Source: <https://www.510kdatabase.net/k250234/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Elastomeric (MEB)
Date received	Jan 27, 2025
Decision date	Apr 24, 2026
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Epic Medical Pte. , Ltd.</b>
Location	Singapore, SG
Contact	Freddie Lee
510(k) history	21 submissions · 21 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250234/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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