

**K151650 SMARTez elastomeric infusion pump**Apr 4, 2016  
291 days to decisionK151650 · Product code: **MEB** · General Hospital  
Source: <https://www.510kdatabase.net/k151650/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Elastomeric (MEB)
Date received	Jun 18, 2015
Decision date	Apr 4, 2016
Days to decision	291 days
Third-party review	Yes
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/k151650/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 3, 2026