

**K141758 T:SLIM INSULIN DELIVERY SYSTEM**Oct 31, 2014  
123 days to decisionK141758 · Product code: **LZG** · General Hospital  
Source: <https://www.510kdatabase.net/k141758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Jun 30, 2014
Decision date	Oct 31, 2014
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tandem Diabetes Care, Inc.</b>
Location	San Diego, CA, US
Contact	JANICE HOGAN
510(k) history	25 submissions · 23 cleared · 2011-2026

Tandem Diabetes Care, Inc. is an American medical device manufacturer based in San Diego, California. The company develops medical technologies for insulin infusion therapy and diabetes treatment. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2011. Chemistry devices represent the dominant category of its regulatory portfolio. The latest FDA 510(k) clearance was granted in 2025, reflecting continued active development and regulatory engagement. Recent cleared devices include the Tandem Mobi insulin pump with interoperabl...

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