

**K143189 t:flex Insulin Delivery System**Jan 9, 2015  
65 days to decisionK143189 · Product code: **LZG** · General Hospital  
Source: <https://www.510kdatabase.net/k143189/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Nov 5, 2014
Decision date	Jan 9, 2015
Days to decision	65 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	John Sheridan
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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