

K111210 T:SLIM (TM) INSULIN DELIVERY SYSTEMNov 9, 2011
194 days to decisionK111210 · Product code: **LZG** · General Hospital
Source: <https://www.510kdatabase.net/k111210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Apr 29, 2011
Decision date	Nov 9, 2011
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tandem Diabetes Care, Inc.
Location	San Diego, CA, US
Contact	DON CANAL
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111210/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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