FDA 510(k) Premarket Notification

CLEARED

K162080 t:slim Insulin Delivery System, t:flex Insulin Delivery System, Tandem Device Updater

Oct 25, 2016
90 days to decision

K162080 · Product code: **LZG** · General Hospital
Source: https://www.510kdatabase.net/k162080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Jul 27, 2016
Decision date	Oct 25, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tandem Diabetes Care, Inc.**
Location	San Diego, CA, US
Contact	Michael Sarrasin
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...