

K122361 T:CONNECT DATA MANAGEMENT SYSTEMFeb 22, 2013
203 days to decisionK122361 · Product code: **OUG** · General Hospital
Source: <https://www.510kdatabase.net/k122361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Device Data System (OUG)
Date received	Aug 3, 2012
Decision date	Feb 22, 2013
Days to decision	203 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.net

Device record: <https://www.510kdatabase.net/k122361/> Data sourced from FDA 510(k) public records (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. - Generated June 9, 2026