FDA 510(k) Premarket Notification

CLEARED

K233044 Tandem Mobi insulin pump with interoperable technology

Oct 5, 2023
10 days to decision

K233044 · Product code: **QFG** · Chemistry
Source: https://www.510kdatabase.net/k233044/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Sep 25, 2023
Decision date	Oct 5, 2023
Days to decision	10 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tandem Diabetes Care, Inc.**
Location	San Diego, CA, US
Contact	Louise Focht
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...