FDA 510(k) Premarket Notification

K243823 Control-IQ+ technology

CLEARED

Feb 24, 2025
74 days to decision

K243823 · Product code: **QJI** · Chemistry
Source: https://www.510kdatabase.net/k243823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Dec 12, 2024
Decision date	Feb 24, 2025
Days to decision	74 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	Christin Dunn
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...

CLINICAL EVIDENCE - NCT05785832

A Randomized Trial Evaluating Control-IQ+ Technology in Adults With Type 2 Diabetes

Status	Completed
Enrollment	319 patients (actual)
Study sites	21 sites
Condition studied	Type 2 Diabetes Treated With Insulin
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Sep 24, 2024
Sponsor	Tandem Diabetes Care, Inc. (Industry)

Primary outcome

HbA1c

Secondary outcome

Time in Range 70-180 mg/dL

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05785832