FDA 510(k) Premarket Notification

K250798 Control-IQ+ technology

CLEARED

May 21, 2025
68 days to decision

K250798 · Product code: **QJI** · Chemistry
Source: https://www.510kdatabase.net/k250798/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Mar 14, 2025
Decision date	May 21, 2025
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Tandem Diabetes Care, Inc.**
Location	San Diego, CA, US
Contact	Miriam Chan
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 - NCT05403502

Safety Evaluation of an Advanced Hybrid Closed Loop System Using Lyumjev With the Tandem t:Slim X2 Insulin Pump With Control-IQ Technology in Adults, Adolescents and Children With Type 1 Diabetes

Status	Completed
Enrollment	183 patients (actual)
Study sites	13 sites
Condition studied	Type 1 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 2, 2023
Sponsor	Tandem Diabetes Care, Inc. (Industry)

Primary outcome

Severe Hypoglycemia

Secondary outcome

Overall Percent Time Less Than 54 mg/dL

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05403502