

K260429 Control-IQ+ technologyApr 24, 2026
73 days to decisionK260429 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k260429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Feb 10, 2026
Decision date	Apr 24, 2026
Days to decision	73 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	Amulya Mallavarapu
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 - NCT04902378**Closed-loop Insulin Delivery In Type 1 Diabetes Pregnancies (CIRCUIT)**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	94 patients (actual)
Study sites	14 sites
Condition studied	Type 1 Diabetes Mellitus; Pregnancy Related; Glucose Metabolism Disorders; Metabolic Disease; Endocrine System Diseases
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	May 23, 2025
Sponsor	University of Calgary (Other)

Primary outcome

Glycemic control as reflected by percent glucose time-in-range

Secondary outcome

Percent time spent above target range per day (+/-SD)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04902378