

## K232382 Control-IQ Technology

Nov 3, 2023  
87 days to decisionK232382 · Product code: **QJI** · Chemistry  
Source: <https://www.510kdatabase.net/k232382/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Aug 8, 2023
Decision date	Nov 3, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Tandem Diabetes Care, Inc.</b>
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 - NCT04796779

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#### The Pediatric Artificial Pancreas (PEDAP) Trial of Control-IQ Technology in Young Children in Type 1 Diabetes

Status	Completed
Enrollment	102 patients (actual)
Study sites	3 sites
Condition studied	Type 1 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jul 31, 2022
Sponsor	Marc Breton (Other)

#### Primary outcome

#### Time in Range

#### Secondary outcome

#### CGM-measured Percent Above 250 mg/dL

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04796779](https://clinicaltrials.gov/study/NCT04796779)