

K200467 Control-IQ Technology

Jun 16, 2020
111 days to decision

K200467 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k200467/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Feb 26, 2020
Decision date	Jun 16, 2020
Days to decision	111 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	Michael Sarrasin
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 - NCT02679287

Project Nightlight: Efficacy and System Acceptance of Dinner/Night vs. 24hr Closed Loop Control

Status	Completed
Enrollment	103 patients (actual)
Study sites	1 site
Condition studied	Diabetes Mellitus, Type 1
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Apr 1, 2019
Sponsor	University of Virginia (Other)

Primary outcome

Time <70 mg/dl by CGM

Secondary outcome

Time Between 70-180 mg/dL by CGM

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02679287