FDA 510(k) Premarket Notification

K251152 DBLG2

CLEARED

Dec 19, 2025
249 days to decision

K251152 · Product code: **QJI** · Chemistry
Source: https://www.510kdatabase.net/k251152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Apr 14, 2025
Decision date	Dec 19, 2025
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Diabeloop**
Location	Grenoble, FR
Contact	Erik Huneker
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT02987556

Diabeloop WP7 : Crossover Evaluation of the Safety and the Efficacy of Artificial Pancreas Diabeloop (WP7)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	71 patients (actual)
Study sites	12 sites
Condition studied	Closed Loop; Diabetes Mellitus, Type 1
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Aug 28, 2018
Sponsor	Centre d'Etudes et de Recherche pour l'Intensification du Traitement du Diabète (Other)

Primary outcome

Percentage of time spent in the tight glycemic control area 70-180 mg/dl continuously measured for 12 weeks

Secondary outcome

Percentage of time spent in the glycemic range 70-180 mg/dl, 80-140 mg/dl and in blood glucose >180 mg/dL during nights and during 24 hours for 12 weeks

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02987556