

K251217 SmartGuard technologyAug 29, 2025
130 days to decisionK251217 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k251217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Apr 21, 2025
Decision date	Aug 29, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	Predictive Low Glucose technology

APPLICANT

Company	Medtronic Minimed, Inc.
Location	Northridge, CA, US
Contact	Hemang Kotecha
510(k) history	8 submissions · 8 cleared · 2007-2026

CLINICAL EVIDENCE - NCT01991470

CEP249 Pediatric Accuracy Study

Status	Completed
Enrollment	186 patients (actual)
Study sites	11 sites
Condition studied	Insulin Requiring Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Sequential
Masking	Open label
Completion date	Dec 1, 2016
Sponsor	Medtronic MiniMed, Inc. (Industry)

Primary outcome

Enlite Sensor Accuracy Mean Absolute Relative Difference (MARD), With Lower Serial Number 530G Pump

Secondary outcome

Enlite 3 Sensor Accuracy Mean Absolute Relative Difference (MARD), With the GST3C Transmitter

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01991470
