FDA 510(k) Premarket Notification

CLEARED

K253585 SmartGuard technology

Jan 14, 2026
58 days to decision

K253585 · Product code: **QJI** · Chemistry
Source: https://www.510kdatabase.net/k253585/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Nov 17, 2025
Decision date	Jan 14, 2026
Days to decision	58 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	Maria Hategan
510(k) history	8 submissions · 8 cleared · 2007-2026

CLINICAL EVIDENCE - NCT05224258

Evaluation of the MiniMed™ 780G System in Type 1 Adult and Pediatric Subjects Utilizing Insulin Fiasp®

Status	Completed
Enrollment	240 patients (actual)
Study sites	18 sites
Condition studied	Type 1 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 21, 2024
Sponsor	Medtronic MiniMed, Inc. (Industry)

Primary outcome

Primary Safety Endpoint - Change in HbA1c

Secondary outcome

Secondary Effectiveness Endpoint 1 - Percent of Time in Hypoglycemia (< 54 mg/dL [3.0 mmol/L])

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05224258