

K253701 SmartGuard TechnologyFeb 3, 2026
71 days to decisionK253701 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k253701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Nov 24, 2025
Decision date	Feb 3, 2026
Days to decision	71 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
Location	Northridge, CA, US
Contact	Shivani Shah
Website	https://www.medtronicdiabetes.com
510(k) history	48 submissions · 43 cleared · 1986-2026

Medtronic Minimed is a diabetes management solutions company based in Northridge, US. The company specializes in insulin delivery and glucose monitoring technologies. Medtronic Minimed has received FDA 510(k) clearances from total submissions since 1986. The company's regulatory focus centers on General Hospital devices, which represent 92% of submissions. Recent clearances in 2026 demonstrate continued active development and regulatory engagement. The company's cleared device portfolio includes insulin infusion pumps, infusion sets, mobile applications for diabetes manag...

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