

K261962 SmartGuard Technology

Jul 9, 2026
28 days to decision

K261962 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k261962/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Jun 11, 2026
Decision date	Jul 9, 2026
Days to decision	28 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	Rushabh Patel
Website	https://www.medtronicdiabetes.com
510(k) history	49 submissions · 44 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...