

K253743 MiniMed Flex pumpMar 12, 2026
108 days to decisionK253743 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k253743/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Nov 24, 2025
Decision date	Mar 12, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

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