

## K241078 Tandem Mobi Insulin Pump with interoperable technology

Jul 26, 2024  
98 days to decisionK241078 · Product code: **QFG** · Chemistry  
Source: <https://www.510kdatabase.net/k241078/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Apr 19, 2024
Decision date	Jul 26, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Tandem Diabetes Care, Inc.</b>
Location	San Diego, CA, US
Contact	Jordan Barkhimer
510(k) history	25 submissions · 23 cleared · 2011-2026

Tandem Diabetes Care, Inc. is an American medical device manufacturer based in San Diego, California. The company develops medical technologies for insulin infusion therapy and diabetes treatment. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2011. Chemistry devices represent the dominant category of its regulatory portfolio. The latest FDA 510(k) clearance was granted in 2025, reflecting continued active development and regulatory engagement. Recent cleared devices include the Tandem Mobi insulin pump with interoperabl...