

K201214 t:slim X2 Insulin Pump with Interoperable TechnologyJun 4, 2020
30 days to decisionK201214 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k201214/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Alternate Controller Enabled Insulin Infusion Pump (QFG) |
| Date received | May 5, 2020 |
| Decision date | Jun 4, 2020 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tandem Diabetes Care, Inc. |
| Location | San Diego, CA, US |
| Contact | Ashley Reynolds |
| 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...