

K251854 SteadiSet infusion setAug 6, 2025
50 days to decisionK251854 · Product code: **FPA** · Chemistry
Source: <https://www.510kdatabase.net/k251854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 17, 2025
Decision date	Aug 6, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tandem Diabetes Care
Location	San Diego, CA, US
Contact	Karen Mudd
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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