

**K242692 SteadiSet Infusion Set**May 9, 2025  
242 days to decisionK242692 · Product code: **FPA** · Chemistry  
Source: <https://www.510kdatabase.net/k242692/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 9, 2024
Decision date	May 9, 2025
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Capillary Biomedical, LLC</b>
Location	Irvine, CA, US
Contact	Kristina Nistler
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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