

**K233350 SINC Support Catheter**Feb 8, 2024  
132 days to decisionK233350 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k233350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 29, 2023
Decision date	Feb 8, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Reflow Medical, Inc.</b>
Location	San Clemente, CA, US
Contact	Lori Grace
510(k) history	9 submissions · 8 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233350/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026