

**K173661 Wingman 35 Crossing Catheter**Apr 18, 2018  
140 days to decisionK173661 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173661/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catheter, Percutaneous (DQY)       |
| Date received         | Nov 29, 2017                       |
| Decision date         | Apr 18, 2018                       |
| Days to decision      | 140 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Reflow Medical, Inc.</b>           |
| Location       | San Clemente, CA, US                  |
| Contact        | Rebecca K Pine                        |
| 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/k173661/> 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 26, 2026