FDA 510(k) Premarket Notification

CLEARED

K193596 Wingman 14, Wingman 14C, Wingman 18, Wingman 35

Feb 20, 2020
59 days to decision

K193596 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k193596/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 23, 2019
Decision date	Feb 20, 2020
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Reflow Medical**
Location	San Diego, CA, US
Contact	Krystal Santiago
510(k) history	10 submissions · 10 cleared · 2010-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k193596/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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