FDA 510(k) Premarket Notification

K173661 Wingman 35 Crossing Catheter

CLEARED

Apr 18, 2018
140 days to decision

K173661 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k173661/

SUBMISSION DETAILS

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

Company	**Reflow Medical, Inc.**
Location	San Clemente, CA, US
Contact	Rebecca K Pine
510(k) history	9 submissions · 8 cleared · 2016-2025