FDA 510(k) Premarket Notification

K173662 speX Support Catheter

CLEARED

Dec 20, 2017
21 days to decision

K173662 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k173662/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 29, 2017
Decision date	Dec 20, 2017
Days to decision	21 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k173662/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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