

K193012 speX Support CatheterFeb 19, 2020
113 days to decisionK193012 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k193012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 29, 2019
Decision date	Feb 19, 2020
Days to decision	113 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

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