FDA 510(k) Premarket Notification

K182553 Inno-Pathwire

CLEARED

Mar 11, 2019
175 days to decision

K182553 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k182553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 17, 2018
Decision date	Mar 11, 2019
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Suzhou Innomed Medical Device Co., Ltd.**
Location	Suzhou, CN
Contact	Irene Ding
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Darlene Garner**
Contact	Darlene Garner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov