

**K182553 Inno-Pathwire**Mar 11, 2019  
175 days to decisionK182553 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182553/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Darlene Garner</b>
Contact	Darlene Garner

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

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