

K193653 Hydrophilic Coating Guide WireAug 26, 2020
240 days to decisionK193653 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k193653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 30, 2019
Decision date	Aug 26, 2020
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Hengrui Disheng Medical Co., Ltd.
Location	Suzhou 215163, CN
Contact	Ling Li
510(k) history	3 submissions · 3 cleared · 2018-2020

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