

K193647 Superpipe Angiographic CatheterJul 29, 2020
212 days to decisionK193647 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k193647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 30, 2019
Decision date	Jul 29, 2020
Days to decision	212 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	Li Ling
510(k) history	3 submissions · 3 cleared · 2018-2020

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