

K171665 Microcatheter and guide-wire systemJan 11, 2018
220 days to decisionK171665 · Product code: **KRA** · CardiovascularSource: <https://www.510kdatabase.net/k171665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Jun 5, 2017
Decision date	Jan 11, 2018
Days to decision	220 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	Jingwen Li
510(k) history	3 submissions · 3 cleared · 2018-2020

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