

**K212719 Micro Catheter and Guidewire System**Apr 11, 2022  
227 days to decisionK212719 · Product code: **KRA** · CardiovascularSource: <https://www.510kdatabase.net/k212719/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Aug 27, 2021
Decision date	Apr 11, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Hengrui Hongyuan Medical Co., Ltd.</b>
Location	Suzhou, CN
Contact	Wang Peipei
510(k) history	2 submissions · 2 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212719/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026