

**K233205 Distal Access Catheter**Dec 22, 2023  
85 days to decisionK233205 · Product code: **QJP** · Neurology  
Source: <https://www.510kdatabase.net/k233205/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Sep 28, 2023
Decision date	Dec 22, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shanghai Heartcare Medical Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Tianrong Hong
510(k) history	3 submissions · 3 cleared · 2021-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233205/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026