FDA 510(k) Premarket Notification

K233205 Distal Access Catheter

CLEARED

Dec 22, 2023
85 days to decision

K233205 · 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	**Shanghai Heartcare Medical Technology Co., Ltd.**
Location	Shanghai, CN
Contact	Tianrong Hong
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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