

K202916 Balloon Guiding CatheterAug 25, 2021
330 days to decisionK202916 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k202916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Sep 29, 2020
Decision date	Aug 25, 2021
Days to decision	330 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	Zongyu Xue
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Tingting Su

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.netDevice record: <https://www.510kdatabase.net/k202916/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026