

K253361 Teleport Glide MicrocatheterApr 10, 2026
192 days to decisionK253361 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k253361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 30, 2025
Decision date	Apr 10, 2026
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	OrbusNeich Medical (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Dora Zhang
510(k) history	9 submissions · 9 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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