FDA 510(k) Premarket Notification

K253361 Teleport Glide Microcatheter

CLEARED

Apr 10, 2026
192 days to decision

K253361 · Product code: **DQY** · Cardiovascular
Source: 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