

K242588 COREPASS Modular Microcatheter (FLEX)Jan 7, 2025
130 days to decisionK242588 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k242588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 30, 2024
Decision date	Jan 7, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	COREPASS Modular Microcatheter (CONTROL)

APPLICANT

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

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