

K210601 Plato 17 MicrocatheterApr 28, 2021
58 days to decisionK210601 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k210601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 1, 2021
Decision date	Apr 28, 2021
Days to decision	58 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Scientia Vascular, LLC
Location	Salt Lake City, UT, US
Contact	Amy McManus
510(k) history	10 submissions · 10 cleared · 2012-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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