

K211990 Rist 071 Radial Access Guide CatheterJul 27, 2021
29 days to decisionK211990 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k211990/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 28, 2021
Decision date	Jul 27, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Location	Lrvine, CA, US
Contact	Amnon Talmor
510(k) history	32 submissions · 32 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	Inneuroco, Inc.
Contact	Marianne Grunwaldt

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

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