

K191551 RIST Cath Radial Access Long SheathDec 23, 2019
194 days to decisionK191551 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k191551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 12, 2019
Decision date	Dec 23, 2019
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rist Neurovascular, Inc.
Location	Miramar, FL, US
Contact	Marianne Grumwaldt
510(k) history	3 submissions · 3 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	Caraballo Consulting
Contact	Elena Jugo

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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