

K211893 SelectFlex Neurovascular Access System FamilyAug 5, 2021
45 days to decisionK211893 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k211893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Jun 21, 2021
Decision date	Aug 5, 2021
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Q&apos;Apel Medical, Inc.
Location	Fremont, AR, US
Contact	Ken Peartree
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Lakeshore Medical Device Consulting
Contact	Michele Lucey

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

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