FDA 510(k) Premarket Notification

CLEARED

K191664 SelectFlex 072 Neurovascular Access System

Aug 30, 2019
70 days to decision

K191664 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k191664/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 21, 2019
Decision date	Aug 30, 2019
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Q'Apel Medical**
Location	Santa Monica, CA, US
Contact	Ken Peartree
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Lakeshore Medical Device Consulting, LLC**
Contact	Michele Lucey

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