

K192525 087 Balloon Guide Catheter SystemOct 31, 2019
48 days to decisionK192525 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k192525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 13, 2019
Decision date	Oct 31, 2019
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Q&apos;Apel Medical, LLC
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](https://accessdata.fda.gov)

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