FDA 510(k) Premarket Notification

K190749 087 Balloon Guide Catheter System

CLEARED

Jul 15, 2019
112 days to decision

K190749 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k190749/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 25, 2019
Decision date	Jul 15, 2019
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Q'Apel**
Location	Santa Monica, CA, US
Contact	Ken Peartree
510(k) history	2 submissions · 2 cleared · 2018-2019

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