FDA 510(k) Premarket Notification

K220716 Spartan SC 069

CLEARED

May 5, 2022
55 days to decision

K220716 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k220716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 11, 2022
Decision date	May 5, 2022
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spartan Micro, Inc.**
Location	Freemont, CA, US
Contact	Gary Avedovech
510(k) history	3 submissions · 3 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Spartan Micro**
Contact	Gary Avedovech

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