FDA 510(k) Premarket Notification

K210358 Neurescue device

CLEARED

May 21, 2021
102 days to decision

K210358 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k210358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Feb 8, 2021
Decision date	May 21, 2021
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurescue Aps**
Location	Copenhagen, DK
Contact	Habib Forest
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	Semih Oktay

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