FDA 510(k) Premarket Notification

K210602 AortaSTAT Occlusion Device

CLEARED

Jul 9, 2021
130 days to decision

K210602 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k210602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Mar 1, 2021
Decision date	Jul 9, 2021
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Renalpro Medical, Inc.**
Location	Santa Clara, CA, US
Contact	James Twitchell
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Northwest Clinical Research Group, Inc.**
Contact	Roberta Hines

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