

**K210602 AortaSTAT Occlusion Device**Jul 9, 2021  
130 days to decisionK210602 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210602/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Northwest Clinical Research Group, Inc.</b>
Contact	Roberta Hines

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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