

K212324 RenovoCathAug 23, 2021
28 days to decisionK212324 · Product code: **MJN** · CardiovascularSource: <https://www.510kdatabase.net/k212324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jul 26, 2021
Decision date	Aug 23, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Renovorx, Inc.
Location	Sunnyvale, CA, US
Contact	Debra Cogan
510(k) history	4 submissions · 4 cleared · 2014-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212324/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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