

# K243601 Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set

May 19, 2025  
179 days to decisionK243601 · Product code: NRY · Neurology  
Source: <https://www.510kdatabase.net/k243601/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Nov 21, 2024
Decision date	May 19, 2025
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Route 92 Medical, Inc.</b>
Location	San Mateo, CA, US
Contact	Kirsten Valley
510(k) history	13 submissions · 13 cleared · 2018-2025

## CLINICAL EVIDENCE - NCT05018650

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### A Randomized, Controlled Trial to Evaluate the Safety and Effectiveness of the Route 92 Medical Reperfusion System (SUMMIT MAX)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	250 patients (actual)
Study sites	30 sites
Condition studied	Acute Ischemic Stroke
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	May 22, 2024
Sponsor	Route 92 Medical, Inc. (Industry)

### Primary outcome

Proportion of subjects with successful arterial revascularization defined as a modified Thrombolysis in Cerebrovascular Infarction (mTICI) score of 2b or greater

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05018650](https://clinicaltrials.gov/study/NCT05018650)