

K233329 Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set

Apr 23, 2024
207 days to decision

K233329 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k233329/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Sep 29, 2023
Decision date	Apr 23, 2024
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k233329/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026