May 19, 2025

Route 92 Medical, Inc.
Kirsten Valley
Chief Operating Officer
155 Bovet Road, Suite 100
San Mateo, California 94402

Re: K243601
Trade/Device Name: Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 14, 2025
Received: April 15, 2025

Dear Kirsten Valley:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243601

Device Name
Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set

Indications for Use *(Describe)*
The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set, when used with a compatible vacuum pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within the internal carotid artery and middle cerebral artery M1 segment within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
K243601

Sponsor:	Route 92 Medical, Inc. 155 Bovet Road, Suite 100 San Mateo, CA 94402 Phone: 650-581-1179
Contact:	Kirsten Valley
Date Prepared:	May 8, 2025
Device Name:	Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever (21 CFR 870.1250)
Product Code	NRY
Device Classification	Class II
Predicate Device:	AXS Vecta Aspiration System, K191768
Reference Devices:	Route 92 Medical 088 Access System, K201518 Route 92 Medical 070 Access System, K203043 Route 92 Medical Full Length 070 Reperfusion System and Aspiration Tubing Set, K223530 8F Modified Sheath System (Route 92 Medical Base Camp Sheath System), K240529 Route 92 Medical Base Camp Sheath System, K191717

Device Description

The Aspiration Catheter, Delivery Catheter, and Base Camp Sheath comprise the Route 92 Medical HiPoint Reperfusion System. The Route 92 Medical HiPoint Reperfusion System is used with the Route 92 Medical Aspiration Tubing Set and the Route 92 Medical Base Camp Sheath System.

The Aspiration Catheter has a single-lumen, coil-reinforced polymer distal shaft section connected to a proximal control wire. The Delivery Catheter is a single-lumen variable stiffness catheter. Both catheters have hydrophilic coating. The devices are provided sterile and non-pyrogenic and are intended for single use only.

The Route 92 Medical Aspiration Tubing Set is made from high-pressure tubing. An on/off switch is provided to control fluid flow. A suction connector allows connection to an aspiration pump canister and a Luer fitting allows connection to the aspiration catheter.

For the aspiration source, the Aspiration Catheter is used in conjunction with an aspiration pump with prespecified performance parameters that is connected using the Route 92 Medical Aspiration Tubing Set.

The Route 92 Medical Base Camp Sheath System is comprised of a Sheath, a Dilator, a Navigating Catheter, and an RHV (rotating hemostasis valve). The Sheath is a single-lumen, variable stiffness catheter with a radiopaque marker on the distal end. The inner lumen of the catheter is compatible with 8 French (F) or smaller catheters. The Dilator may be placed within the Sheath to facilitate percutaneous introduction of the Sheath into a femoral artery. The Dilator has a radiopaque marker at the distal tip. The Navigating Catheter is a single-lumen, variable stiffness catheter with a radiopaque marker at the distal tip. The Navigating Catheter is compatible with the Sheath and has a shaped distal end to facilitate placement. All of the catheters are coated with hydrophilic coating.

Indications for Use

The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set, when used with a compatible vacuum pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within the internal carotid artery and middle cerebral artery M1 segment within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Comparison to the Predicate Device

The method of action, design, and materials of the Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set are substantially equivalent to the predicate device as shown in the following table.

Attribute	**Predicate Device** K191768, AXS Vecta Aspiration System (Stryker Neurovascular)	**Subject Device** K243601, Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (Route 92 Medical)
Indications for Use	The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System, is indicated in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-	The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set, when used with a compatible vacuum pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within the internal carotid artery and middle cerebral artery M1 segment within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who

Attribute	**Predicate Device** K191768, AXS Vecta Aspiration System (Stryker Neurovascular)	**Subject Device** K243601, Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (Route 92 Medical)
	PA therapy are candidates for treatment.	failed thrombolytic drug therapy are candidates for treatment.
Device Description	The AXS Vecta Aspiration Catheter is a variable stiffness catheter with a continuous polymer shaft. A Scout Introducer to facilitate delivery is provided.	The Aspiration Catheter is a variable stiffness catheter with a distal polymer shaft section connected to a proximal control wire. A Delivery Catheter to facilitate delivery of the Aspiration Catheter is provided. The HiPoint Reperfusion System is used with the Route 92 Medical Aspiration Tubing Set and the Route 92 Medical Base Camp Sheath System.
User	Physicians trained in neurovascular interventional techniques	Same
Anatomical Sites	Neurovasculature only	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same
Sterilization	Ethylene oxide	Same
Aspiration Catheter		
Inner Diameter (nominal)	0.074” (Vecta 74) 0.071” (Vecta 71)	0.088” (88 Aspiration Catheter) 0.070” (70 Aspiration Catheter)
Outer Diameter (nominal)	0.083” distal / 0.087” proximal (Vecta 74) 0.082” distal / 0.085” proximal (Vecta 71)	0.101” distal / 0.105” proximal (88 Aspiration Catheter) 0.082” distal / 0.087” proximal (70 Aspiration Catheter)
Length	115, 125, 132 cm	143 cm (88 Aspiration Catheter) 142 cm (70 Aspiration Catheter)
Delivery Catheter		
Inner Diameter	0.044”	0.019”
Outer Diameter	0.058”	0.080” distal /0.062” proximal (88 Delivery Catheter) 0.062” (70 Delivery Catheter)

Attribute	Predicate Device K191768, AXS Vecta Aspiration System (Stryker Neurovascular)	Subject Device K243601, Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (Route 92 Medical)
Length	133, 143, 150 cm	151 cm
Compatibility: Pump for Aspiration	Medela Dominant Flex Pump or equivalent	Portable vacuum pump designed for use in the hospital setting that is capable of providing a constant vacuum of -25 inHg to -27.5 inHg.
Aspiration Tubing	AXS Universal Aspiration Tubing	Route 92 Medical Aspiration Tubing Set (K223530)

Non-Clinical Testing

Shelf Life and Sterility

The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of 1×10^{-6} in accordance with ISO 11135. Aging studies established that the subject device and packaging remain functional for the labeled expiration date.

Biocompatibility Testing

The patient-contacting materials of the Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set were unchanged compared to the reference devices K201518, K203043, K223530, K191717, and K240529; therefore, no additional biocompatibility testing was required.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical HiPoint Reperfusion System is suitable for its intended use.

Test	Test Method	Results
Simulated Use Testing	Deliverability, clot retrieval, device integrity, kink and aspiration resistance, lumen patency, durability and compatibility with accessory devices were evaluated in a neurovascular model.	**PASS** All samples met the pre-determined acceptance criteria
Lumen Patency Testing	Test specimens were tested for lumen patency under vacuum.	**PASS** All samples met the pre-determined acceptance criteria
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications.	**PASS** All samples met the pre-determined acceptance criteria

Test	Test Method	Results
Luer Integrity	Tested per ISO 80369-7:2021.	**PASS** All samples met the pre-determined acceptance criteria
Tensile Strength	The tensile strength of the catheter sections and bonds was tested.	**PASS** All samples met the pre-determined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance.	**PASS** All samples met the pre-determined acceptance criteria
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation.	**PASS** All samples met the pre-determined acceptance criteria
Tip Flexibility	Test specimens were tested for tip flexibility.	**PASS** All samples met the pre-determined acceptance criteria
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	**PASS** All samples met the pre-determined acceptance criteria
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	**PASS** All samples met the pre-determined acceptance criteria
Static Burst	Tested per ISO 10555-1:2013 Annex F.	**PASS** All samples met the pre-determined acceptance criteria
Dynamic Burst	Mechanical integrity was assessed under pressure.	**PASS** All samples met the pre-determined acceptance criteria
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles.	**PASS** All samples met the pre-determined acceptance criteria
Aspiration Pressure	The vacuum pressure at the tip of the catheter was assessed during aspiration.	**PASS** All samples met the pre-determined acceptance criteria
Particulate	The size and quantity of particulates generated during simulated use were evaluated.	**PASS** All samples met the pre-determined acceptance criteria

Animal Studies

A chronic animal study was conducted according to good laboratory practices (GLP) in a swine model to demonstrate the safety and performance of the Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set to establish substantial equivalence to the predicate device. Study animals were terminated at either subacute (3-day) or chronic (30-day) time points. Devices were evaluated under worst-case clinical conditions, including soft and firm clot aspiration, wedge aspiration, downstream organ assessment, and in-life observations. Postmortem assessment of treated vessels was performed. The study findings for the Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set were comparable to the predicate device demonstrating substantial equivalence.

Clinical Studies

Summary

SUMMIT MAX was a prospective, multi-center, randomized, controlled, interventional, open-label clinical trial evaluating safety and effectiveness of the Route 92 Medical HiPoint Reperfusion System for removing occlusions in acute ischemic stroke patients as compared to a predicate device (AXS Vecta Aspiration System).

Patient Population

Key inclusion criteria were as follows: age 18 and older, baseline National Institutes of Health Stroke Scale (NIHSS) ≥ 6, pre-stroke modified Rankin Scale (mRS) of 2 or less, baseline Alberta Stroke Program Early CT Score (ASPECTS) ≥ 6, and endovascular treatment initiated within 8 hours of symptom onset. Angiographic confirmation of a middle cerebral artery (MCA) M1 segment or internal carotid artery (ICA) occlusion was required. Intravenous thrombolysis was allowed. Complete inclusion and exclusion criteria are listed below.

Inclusion Criteria

1. The consent process has been completed and documented according to applicable country regulations and as approved by the IRB / Ethics Committee.
2. Age ≥18 years.
3. Patient presenting with clinical signs consistent with an acute ischemic stroke.
4. Baseline National Institutes of Health Stroke Scale (NIHSS) score ≥ 6.
5. Pre-stroke modified Rankin Score (mRS) ≤ 2.
6. Baseline ASPECTS ≥ 6.
7. Endovascular treatment initiated (defined as time of groin puncture) within 8 hours from time last known well.
8. If indicated, thrombolytic therapy shall be initiated per clinical guidelines. If eligible for thrombolytic therapy, subjects should be treated as soon as possible, and lytic use should not be delayed regardless of potential eligibility for mechanical neurothrombectomy.
9. The patient was indicated for aspiration neurothrombectomy with the Route 92 Medical Reperfusion System as determined by the Investigator.

Angiographic Inclusion Criteria

10. Angiographic confirmation of a large vessel occlusion of the M1 segment of the middle cerebral artery or distal internal carotid artery (patency of the cervical ICA to the origin

of the ophthalmic artery).

Exclusion Criteria

1. Known pregnancy or breast feeding.
2. In the Investigator's opinion, any known comorbidity (including COVID-19 positivity) that may complicate treatment or prevent improvement or follow-up.
3. Known serious, advanced, or terminal illness with anticipated life expectancy < 12 months.
4. Known history of severe allergy to contrast medium.
5. Known to have suffered a stroke in the past 90 days.
6. Known connective tissue disorder affecting the arteries (e.g., Marfan syndrome, Ehlers-Danlos syndrome).
7. Any known previous cerebral hemorrhagic event.
8. Any known pre-existing coagulation deficiency.
9. Known hemorrhagic diathesis, coagulation factor deficiency, or oral anticoagulant therapy with INR > 3.0.
10. Known baseline platelet count < 50,000/μL
11. Known baseline blood glucose of < 50 mg/dL or > 400 mg/dL.
12. Known to be participating in another study involving an investigational device or drug.
13. Clinical symptoms suggestive of bilateral stroke or stroke in multiple territories.
14. Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) evidence of recent/fresh cerebral hemorrhage (the presence of microbleeds was allowed).
15. Baseline CT or MRI showing intracranial tumor (except small meningioma ≤ 2 cm) or significant mass effect with midline shift due to the tumor.
16. Presumed septic thrombus, or suspicion of bacterial endocarditis.
17. Inability to access the cerebral vasculature in the opinion of the neurointerventional team.
18. Unlikely to be available for a 90-day follow-up (e.g., no fixed home address).
19. Evidence of arterial dissection in a vessel that must be traversed.
20. Evidence of high-grade stenosis or occlusion (i.e., tandem occlusion) in a vessel that must be traversed.
21. Known active or recent history of cocaine or methamphetamine abuse (within last 6 months).
22. Known history or presence of aneurysm or arteriovenous malformation (AVM) in the territory of the target lesion.
23. For all patients, severe sustained (15 minutes or more) hypertension with SBP > 200 and/or DBP >120; for patients treated with a lytic, sustained hypertension despite treatment with SBP >185 and/or DBP >110.
24. Treatment with heparin within 48 hours with a partial thromboplastic time more than two times the laboratory normal or treatment with any low molecular weight heparin (LMWH) within 48 hours.
25. Renal failure with serum creatinine >3.0 or Glomerular Filtration Rate (GFR) < 30.
26. Ongoing seizure due to stroke.
27. Evidence of active systemic infection.
28. Known cancer with metastases.

Angiographic Exclusion Criteria

29. Angiographic evidence of a dissection in the extracranial or intracranial cerebral arteries.
30. Arterial stenosis requiring balloon angioplasty or stenting at the time of the procedure.
31. Angiographic evidence of multiple cerebrovascular occlusions (e.g., bilateral anterior circulation, anterior/posterior circulation, tandem occlusion).
32. Angiographic evidence of known or suspected underlying intracranial vasculopathy or atherosclerotic lesions responsible for the target occlusion.
33. Angiographic evidence or suspicion of aortic dissection.
34. Angiographic evidence of an aneurysm or arteriovenous malformation (AVM) in the territory of the target lesion.

Analysis Populations

Different analysis populations were identified depending on the type and extent of analysis being performed. The endpoints were analyzed using the "Modified Intent to Treat Cohort."

- Intent to Treat (ITT) Cohort
  All randomized subjects.
- Modified Intent to Treat (mITT) Cohort
  Subjects from the ITT cohort who met inclusion and exclusion criteria and for whom the index procedure was planned, or an attempt was made to perform the index procedure, independent of the success of the procedure.
- Per-Protocol Cohort
  All subjects in the mITT cohort in whom there were no major protocol deviations or violations that may have an effect on the integrity of the study data and in whom the procedure was completed.

Disposition of Participants

Of the 250 patients that were enrolled, 50 did not meet the inclusion/exclusion criteria prior to randomization. The remaining 200 patients were randomized (N=107 Route 92 arm, N=93 Vecta arm) and comprise the intent-to-treat randomized cohort (ITT Randomized).

This ITT Randomized cohort included patients who did not meet the inclusion/exclusion criteria after randomization (e.g., no occlusion on angiogram). As a result of not meeting the inclusion/exclusion criteria, 19 participants did not undergo the study procedure with an investigational device or control device after randomization.

The 181 participants (N=97 Route 92 arm, N=84 Vecta arm) who were randomized and attempted treatment with a study or control device comprise the "ITT Randomized and Treated" cohort. This is the population for whom procedure and outcome data are available. Of the 181 "ITT Randomized and Treated" patients, an additional 15 participants did not meet the inclusion/exclusion criteria resulting in 166 participants who were randomized, attempted treatment, and met the inclusion/exclusion criteria. The most common reasons for exclusion of these patients were treatment not within 8 hours (n=5) and no confirmation of a large vessel occlusion (n=3). These 166 participants (N=89 Route 92 arm, N=77 Vecta arm) comprise the modified intent-to-treat cohort (mITT). The treated patients in this cohort include those

in whom the use of the study or control device was attempted regardless of success. There were six patients with major protocol deviations that had an effect on the integrity of the data resulting in 160 participants (N=85 Route 92 arm, N=75 Vecta arm) in the per-protocol cohort (PP). Of the six patients with major protocol deviations that had an effect on the integrity of the data, two were randomization errors in which the patient was randomized to the Vecta arm but the site mistakenly used the Route 92 Medical device. For the other four patients, the operator failed to use the assigned device and instead used adjunctive therapy due to guide sheath incompatibility issues.

Subject Follow-up

Patients were followed for 90 days with endpoint evaluations at 24 hours (sICH) and 90 days (modified Rankin Scale score). As shown below, the 24-hour assessment was completed in 99.4% (165/166) of patients. The 90-day assessment was completed in 97.6% (162/166) of patients. Patients who expired prior to the 90-day assessment were considered to have completed the study.

Subject Disposition	**Overall (N=166)**	**Route 92 (N=89)**	**Vecta (N=77)**
Subjects who completed 24-hour assessment	99.4% (165/166)	98.9% (88/89)	100.0% (77/77)
Discontinued	2.4% (4/166)	2.2% (2/89)	2.6% (2/77)
Lost-to-follow-up	1.2% (2/166)	1.1% (1/89)	1.3% (1/77)
Subject withdrew consent	0.6% (1/166)	0.0% (0/89)	1.3% (1/77)
90-day assessment missed (site error)	0.6% (1/166)	1.1% (1/89)	0.0% (0/77)
Subjects who completed the study (90-day follow up)	97.6% (162/166)	97.8% (87/89)	97.4% (75/77)

Baseline Demographics

Characteristic	**Overall (N=166)**	**Route 92 (N=89)**	**Vecta (N=77)**
Gender Female, % (n/N)	54.2% (90/166)	56.2% (50/89)	51.9% (40/77)
Age			
N	166	89	77
Mean (SD)	67.0 (14.2)	68.6 (13.5)	65.1 (14.8)
Median	69.0	71.0	66.0
Min, Max	18.0, 94.0	33.0, 94.0	18.0, 90.0
Race, % (n/N)			
American Indian or Alaska Native	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Asian	4.2% (7/166)	3.4% (3/89)	5.2% (4/77)
Black or African American	10.2% (17/166)	9.0% (8/89)	11.7% (9/77)
Native Hawaiian or Other Pacific Islander	0.6% (1/166)	0.0% (0/89)	1.3% (1/77)
White	77.7% (129/166)	75.3% (67/89)	80.5% (62/77)
Maori	0.6% (1/166)	1.1% (1/89)	0.0% (0/77)

Characteristic	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Other	2.4% (4/166)	3.4% (3/89)	1.3% (1/77)
Declined to Answer/Unknown	4.2% (7/166)	7.9% (7/89)	0.0% (0/77)
Hispanic or Latino Ethnicity	7.2% (12/166)	9.0% (8/89)	5.2% (4/77)
Baseline ASPECTS			
N	166	89	77
Mean (SD)	8.9 (1.3)	9.0 (1.3)	8.8 (1.2)
Median	9.0	10.0	9.0
Min, Max	6.0, 10.0	6.0, 10.0	6.0, 10.0
Pre-stroke mRS, % (n/N)			
0	80.7% (134/166)	79.8% (71/89)	81.8% (63/77)
1	15.1% (25/166)	16.9% (15/89)	13.0% (10/77)
2	4.2% (7/166)	3.4% (3/89)	5.2% (4/77)
Baseline NIHSS Score			
N	166	89	77
Mean (SD)	17.0 (5.8)	16.7 (5.6)	17.3 (6.0)
Median	17.0	16.0	18.0
Min, Max	6.0, 30.0	6.0, 29.0	6.0, 30.0
Last Known Well to Arterial Puncture (Hours)			
N	166	89	77
Mean (SD)	4.1 (1.8)	4.0 (1.8)	4.2 (1.7)
Median	3.8	3.6	4.2
Min, Max	1.3, 8.0	1.3, 7.9	1.4, 8.0
Medical History, % (n/N)[1]			
Hypertension	77.2% (125/162)	84.9% (73/86)	68.4% (52/76)
Heart Failure	21.3% (35/164)	20.7% (18/87)	22.1% (17/77)
Coronary Artery Disease	22.4% (36/161)	22.4% (19/85)	22.4% (17/76)
Carotid Artery Disease	2.5% (4/160)	3.5% (3/85)	1.3% (1/75)
Atrial Fibrillation	42.3% (69/163)	44.2% (38/86)	40.3% (31/77)
Patent Foramen Ovale	2.5% (4/163)	1.1% (1/87)	3.9% (3/76)
Hematologic Disorder	3.0% (5/164)	3.4% (3/87)	2.6% (2/77)
Previous Intracerebral Hemorrhage	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Peripheral Vascular Disease	5.6% (9/160)	7.1% (6/85)	4.0% (3/75)
Diabetes Mellitus	24.4% (40/164)	19.3% (17/88)	30.3% (23/76)
Kidney Disease	10.4% (17/164)	10.3% (9/87)	10.4% (8/77)
Seizures	2.4% (4/164)	2.3% (2/87)	2.6% (2/77)
Dyslipidemia	59.6% (99/166)	66.3% (59/89)	51.9% (40/77)
Current Smoker	16.5% (26/158)	14.5% (12/83)	18.7% (14/75)
Past Smoker	20.8% (33/159)	15.5% (13/84)	26.7% (20/75)
Previous TIA	9.1% (15/165)	9.1% (8/88)	9.1% (7/77)
Previous Ischemic Stroke	12.1% (20/165)	10.2% (9/88)	14.3% (11/77)

[1]Denominators reflective of patients without missing medical history data for a given medical history covariate. Patients with missing data not included in the denominator.

Occlusion Location and Procedural Characteristics

Occlusion Location	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Angiographically confirmed baseline occlusion location, % (n/N)			
ICA	12.7% (21/166)	13.5% (12/89)	11.7% (9/77)
M1	87.3% (145/166)	86.5% (77/89)	88.3% (68/77)
Side of occlusion, % (n/N)			
Left	47.0% (78/166)	49.4% (44/89)	44.2% (34/77)
Right	53.0% (88/166)	50.6% (45/89)	55.8% (43/77)

Procedural Characteristics	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Adjunctive therapy, % (n/N)			
Use of adjunctive therapy at site of occlusion, % (n/N)[2]	33.7% (56/166)	20.2% (18/89)	49.4% (38/77)
Alternative aspiration catheter (AC)	21.1% (35/166)	14.6% (13/89)	28.6% (22/77)
Stent retriever (SR)	27.1% (45/166)	15.7% (14/89)	40.3% (31/77)
IA lytic	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Other	2.4% (4/166)	1.1% (1/89)	3.9% (3/77)
Number of Passes			
N	166	89	77
Mean (SD)	2.3 (1.9)	2.0 (1.7)	2.8 (2.1)
Median	1.0	1.0	2.0
Min, Max	1.0, 10.0	1.0, 9.0	1.0, 10.0
Procedure Time (Time from Groin Puncture to Groin Closure), mins			
N	166	89	77
Mean (SD)	57.4 (47.9)	57.8 (56.3)	56.9 (36.2)
Median	42.0	40.0	47.0
Min, Max	10.0, 427.0	10.0, 427.0	10.0, 178.0
IV Lytic, % (n/N)			
TNK	39.8% (66/166)	43.8% (39/89)	35.1% (27/77)
t-PA	18.7% (31/166)	16.9% (15/89)	20.8% (16/77)
Not administered	41.6% (69/166)	39.3% (35/89)	44.2% (34/77)
Anesthesia, % (n/N)[2]			
General anesthesia	53.0% (88/166)	46.1% (41/89)	61.0% (47/77)
IV sedation	27.1% (45/166)	32.6% (29/89)	20.8% (16/77)
General anesthesia and IV sedation	1.8% (3/166)	1.1% (1/89)	2.6% (2/77)
Other	18.1% (30/166)	20.2% (18/89)	15.6% (12/77)

[2] Not mutually exclusive, subjects may fall into more than one sub-category.

Endpoints

The primary effectiveness endpoint was successful reperfusion (defined as mTICI ≥ 2b, adjudicated by an independent blinded core lab) using only the assigned study device, with use of any adjunctive therapy either before or after use of the study device considered a failure.

The primary safety endpoint was symptomatic intracranial hemorrhage (sICH) within 24 h (-8/+24) post-procedure, defined by the Heidelberg bleeding classification. Intracranial hemorrhage was identified by the core lab and adjudicated by the clinical events committee.

Results

Both the primary effectiveness endpoint and the primary safety endpoint were met. Specifically, the effectiveness endpoint of revascularization rate (with adjunctive therapy counted as a failure) achieved by the subject device (77.5% [69/89]) was non-inferior to the revascularization rate achieved by the predicate device (50.6% [39/77]).

Endpoint	**Route 92 (N=89)**	**Vecta (N=77)**	**Difference (95% Confidence Interval)[3]**	**P-value[4]**
Successful arterial revascularization, any adjunctive therapy considered a failure, % (n/N)	77.5% (69/89)	50.6% (39/77)	26.9% (12.7%, 41.0%)	< 0.0001

[3] Wald confidence interval.
[4] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%. The one-sided p-value from a two-sample Z-test for proportions in a superiority context is 0.0001.

The clinical protocol limited the use of the Route 92 Medical HiPoint Reperfusion System to three passes. Additional analyses of the primary effectiveness endpoint that consider more than three passes as a failure were also performed:

Endpoint	**Route 92 (N=89)**	**Vecta (N=77)**	**Difference (95% Confidence Interval)[5]**	**P-value[6]**
Successful arterial revascularization, any adjunctive therapy and > 3 passes considered a failure, % (n/N)	76.4% (68/89)	48.1% (37/77)	28.4% (14.1%, 42.6%)	< 0.0001

[5] Wald confidence interval.
[6] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%. The one-sided p-value from a two-sample Z-test for proportions in a superiority context is 0.0001.

Similarly, the primary safety endpoint of symptomatic intracranial hemorrhage (sICH) at 24 hours as adjudicated by an independent, blinded core lab and similarly blinded and independent clinical events committee was 3.6% (93/84) with the subject device as compared to 2.7% (2/75) with the predicate device which was non-inferior.

Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% Confidence Interval)[7]	P-value[8]
Incidence of symptomatic intracranial hemorrhage (sICH) within 24 (-8/+ 24) hours post-procedure, % (n/N)	3.6% (3/84)	2.7% (2/75)	0.9% (-4.5%, 6.3%)	< 0.0001

[7] Wald confidence interval.
[8] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%.

At 90 days, good clinical outcome (mRS ≤ 2) was achieved in 50.6% of patients treated with the subject device as compared to 53.3% of patients treated with the predicate device. The overall incidence of any hemorrhage within 24 (-8/+24) hours post-procedure as adjudicated by the independent, blinded core lab was 42.7% (38/89) for the subject device as compared to 49.4% (38/77) for the predicate device. Other secondary endpoints are shown below.

Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% CI)[13]
Successful arterial revascularization after use of assigned device, subsequent use of adjunctive therapy not counted as failure, % (n/N)[9]	80.9% (72/89)	70.1% (54/77)	10.8% (-2.3%, 23.9%)
Device-related SAEs, % (n/N) [10]	5.6% (5/89)	2.6% (2/77)	3.0% (-2.9%, 9.0%)
Good clinical outcome (mRS ≤ 2 at 90-day follow-up visit), % (n/N)	50.6% (44/87)	53.3% (40/75)	-2.8% (-18.2%, 12.7%)
Incidence of all intracranial hemorrhages within 24 (-8/+24) hours post-procedure, % (n/N)[11]	42.7% (38/89)	49.4% (38/77)	-6.7% (-21.8%, 8.5%)
Time from groin puncture to final angiogram (minutes), mean	41.82	47.12	5.31 (-5.86, 16.47)
Proportion of subjects with First Pass Effect (mTICI ≥ 2b) (FPE), % (n/N)[12]	60.5% (52/86)	54.5% (36/66)	5.9% (-9.9%, 21.8%)

[9] Successful arterial revascularization is defined as a modified Thrombolysis in Cerebrovascular Infarction (mTICI) score of 2b or greater, as judged by an independent adjudicating core laboratory, after last pass with assigned device. If an mTICI score of 2b or greater was achieved after use of the assigned device, subsequent use of IA lytic or another mechanical neurothrombectomy device other than the assigned device is not counted as a failure.
[10] As adjudicated by the CEC.
[11] ICH identified by the independent adjudicating core laboratory.
[12] FPE defined as achievement of successful recanalization (mTICI ≥ 2b) as judged by an independent adjudicating core laboratory after the first pass with only the assigned device.
[13] Nominal two-sided 95% confidence intervals (i.e., Wald confidence intervals) are reported for differences in proportions and for difference in means.

All intracranial hemorrhages were reviewed and classified by the core lab.

	Route 92 % (n/N)	**Vecta % (n/N)**
All Intracranial Hemorrhages	42.7% (38/89)	49.4% (38/77)
PH2	0.0% (0/89)	0.0% (0/77)
SAH	3.4% (3/89)	3.9% (3/77)
SAH + PH1	0.0% (0/89)	0.0% (0/77)
HI1	16.9% (15/89)	23.4% (18/77)
HI2	11.2% (10/89)	9.1% (7/77)
RIH	0.0% (0/89)	1.3% (1/77)
PH1 + HI2	1.1% (1/89)	0.0% (0/77)
RIH + HI1	0.0% (0/89)	1.3% (1/77)
SAH + HI1	3.4% (3/89)	7.8% (6/77)
SAH + HI2	0.0% (0/89)	1.3% (1/77)
SAH + RIH	1.1% (1/89)	0.0% (0/77)
SAH + IVH	2.2% (2/89)	0.0% (0/77)
SAH + IVH + PH1	1.1% (1/89)	0.0% (0/77)
SAH + HI2+ PH2	0.0% (0/89)	1.3% (1/77)
SAH + IVH + PH2	1.1% (1/89)	0.0% (0/77)
PH-1 + SAH + IVH + HI-2	1.1% (1/89)	0.0% (0/77)

***Note:** The overall rate of core lab adjudicated subarachnoid hemorrhage (SAH) in the SUMMIT MAX trial included 12/89 (13.5%) of subjects in the Route 92 arm and 11/77 (14.3%) of the Vecta arm.

****Note:** Within the Route 92 arm, 1/12 subjects with SAH were not treated with any Route 92 devices; 7/11 subjects with SAH treated with Route 92 devices were treated with 1-2 passes of the 88 Aspiration Catheter alone; 8/11 subjects with SAH were treated with Route 92 devices for 1-2 passes without use of adjunctive devices; the average number of passes was 2.8 in the 11 subjects with SAH in the Route 92 arm. SAH incidence in subjects where only the Route 92 devices were used for mechanical neurothrombectomy in the Route 92 arm was 8/89 (9%).
Within the Vecta arm, 2/11 subjects with SAH were treated with 1-2 passes of the Vecta catheters, and 9/11 subjects with SAH were treated with adjunctive devices and multiple passes, with an average of 5.8 passes in the 11 subjects with SAH in the Vecta arm. SAH incidence in subjects where only the Vecta devices were used for mechanical neurothrombectomy in the Vecta arm was 2/77 (2.6%).

Adverse Events

AE Name	**Route 92 % (n/N)**	**Vecta % (n/N)**
Nervous system disorders	49.4% (44/89)	53.2% (41/77)
Cerebral haemorrhage	12.4% (11/89)	9.1% (7/77)
Headache	9.0% (8/89)	11.7% (9/77)
Cerebral infarction	6.7% (6/89)	7.8% (6/77)
Cerebral vasoconstriction	9.0% (8/89)	9.1% (7/77)
Brain oedema	13.5% (12/89)	1.3% (1/77)
Subarachnoid haemorrhage	6.7% (6/89)	2.6% (2/77)
Cerebrovascular accident	2.2% (2/89)	6.5% (5/77)
Haemorrhagic transformation stroke	5.6% (5/89)	2.6% (2/77)

AE Name	Route 92 % (n/N)	Vecta % (n/N)
Intracranial artery dissection	2.2% (2/89)	1.3% (1/77)
Stroke in evolution	2.2% (2/89)	1.3% (1/77)
Syncope	2.2% (2/89)	1.3% (1/77)
Cerebral artery occlusion	3.4% (3/89)	0.0% (0/77)
Dizziness	2.2% (2/89)	1.3% (1/77)
Intraventricular haemorrhage	2.2% (2/89)	1.3% (1/77)
Carotid artery occlusion	1.1% (1/89)	1.3% (1/77)
Encephalopathy	2.2% (2/89)	0.0% (0/77)
Haemorrhage intracranial	2.2% (2/89)	0.0% (0/77)
Neuralgia	1.1% (1/89)	1.3% (1/77)
Seizure	0.0% (0/89)	2.6% (2/77)
Somnolence	1.1% (1/89)	1.3% (1/77)
Aphasia	0.0% (0/89)	1.3% (1/77)
Basal ganglia infarction	0.0% (0/89)	1.3% (1/77)
Basal ganglia stroke	1.1% (1/89)	0.0% (0/77)
Carotid artery dissection	0.0% (0/89)	1.3% (1/77)
Cerebral atrophy	0.0% (0/89)	1.3% (1/77)
Cerebral mass effect	0.0% (0/89)	1.3% (1/77)
Cerebrovascular pseudoaneurysm	1.1% (1/89)	0.0% (0/77)
Cognitive disorder	0.0% (0/89)	1.3% (1/77)
Cytotoxic oedema	1.1% (1/89)	0.0% (0/77)
Depressed level of consciousness	1.1% (1/89)	0.0% (0/77)
Grimacing	1.1% (1/89)	0.0% (0/77)
Intracranial aneurysm	0.0% (0/89)	1.3% (1/77)
Intracranial mass	1.1% (1/89)	0.0% (0/77)
Ischaemic stroke	0.0% (0/89)	1.3% (1/77)
Lethargy	1.1% (1/89)	0.0% (0/77)
Memory impairment	0.0% (0/89)	1.3% (1/77)
Metabolic encephalopathy	1.1% (1/89)	0.0% (0/77)
Restless legs syndrome	1.1% (1/89)	0.0% (0/77)
Vagus nerve disorder	1.1% (1/89)	0.0% (0/77)

Conclusion

The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set has the same intended use, similar technological characteristics, and same method of action as the predicate device. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness of the device. The successful completion of non-clinical testing and the findings of the clinical study demonstrate that the Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set is substantially equivalent to the predicate device.