April 23, 2024

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

Re: K233329
Trade/Device Name: Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: March 24, 2024
Received: March 25, 2024

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.

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)*
K233329

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

Indications for Use *(Describe)*
The Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set is indicated for use 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-PA 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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K233329 510(K) SUMMARY

Sponsor:	Route 92 Medical, Inc. 155 Bovet Road, Suite 100 San Mateo, CA 94402 Phone: 650-581-1179
Contact:	Kirsten Valley
Date Prepared:	April 21, 2024
Device Name:	Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever (Product Code NRY, 21 CFR 870.1250)
Device Classification	Class II
Predicate Device:	Penumbra Reperfusion Catheter 054 and Penumbra Separator 054, K090752
Reference Devices:	Route 92 Medical Full Length 054 Access System, K231583 Route 92 Medical Full Length 070 Reperfusion System and Aspiration Tubing Set, K223530

Device Description

The 054 Aspiration Catheter and Tenzing 5 Delivery Catheter comprise the Route 92 Medical Full Length 054 Reperfusion System. The Route 92 Medical Full Length 054 Reperfusion System is used with the Route 92 Medical Aspiration Tubing Set.

The 054 Aspiration Catheter is a single-lumen, coil-reinforced variable stiffness catheter. The Tenzing 5 Delivery Catheter is a single-lumen variable stiffness catheter. Both catheters are hydrophilically coated. 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, along with a legally marketed canister and accessories kit.

Indications for Use

The Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set is indicated for use 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-PA therapy are candidates for treatment.

Comparison to the Predicate Device

The method of action, design, and materials of the Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set are substantially equivalent to the predicate device as shown in the following table.

Attribute	**Predicate Device** Penumbra Reperfusion Catheter 054 and Penumbra Separator 054 (K090752)	**Subject Device** Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set (K233329)
Indications for Use	The Penumbra System is intended for use 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.	The Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set is indicated for use 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-PA therapy are candidates for treatment.
Device Description	The Penumbra System consists of three devices that work as a system to remove thrombus including the Penumbra Reperfusion Catheter, Penumbra Separator and Aspiration Tubing. The Penumbra System is used with the Penumbra Aspiration Pump.	The Route 92 Medical Full Length 054 Reperfusion System includes the 054 Aspiration Catheter and Tenzing 5 Delivery Catheter and is used with the Route 92 Medical Aspiration Tubing Set. The devices are sterile, non-pyrogenic, and intended for single use only.
User	Physicians trained in neurovascular interventional techniques	Same

Attribute	**Predicate Device** Penumbra Reperfusion Catheter 054 and Penumbra Separator 054 (K090752)	**Subject Device** Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set (K233329)
Anatomical Sites	Neurovasculature only	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same
Sterilization	Ethylene oxide	Same
Shelf-life	3 years	6 months
Aspiration Catheter		
Inner Diameter (nominal)	0.054”	0.054”
Outer Diameter (nominal)	0.064”	0.066”
Length	135 cm	125 cm and 148 cm
Delivery Catheter		
Inner Diameter	Not applicable	0.019” proximal 0.015” distal
Outer Diameter	Not applicable	0.048”
Length	Not applicable	167 cm
Compatibility: Pump for Aspiration	Penumbra Pump MAX	Commercially available vacuum pump designed for use in hospital settings that is compatible with the Route 92 Medical Reperfusion System and provides a constant vacuum of -25 inHg to -27.5 inHg.
Aspiration Tubing		
Inner Diameter	0.71”-0.110”	0.110”
Outer Diameter	Not available	0.188”
Length	112”	112”

Attribute	Predicate Device Penumbra Reperfusion Catheter 054 and Penumbra Separator 054 (K090752)	Subject Device Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set (K233329)
Materials	Biocompatible materials, commonly utilized for interventional devices	Same

Non-Clinical Testing

Shelf Life and Sterility

The Route 92 Medical Full Length 054 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 Full Length 054 Reperfusion System and Aspiration Tubing Set were unchanged compared to the reference device K223530; therefore, no additional biocompatibility testing was required.

Performance Testing

The successful completion of the performance testing listed in the following tables demonstrates that the Route 92 Medical Full Length 054 Reperfusion System is suitable for its intended use.

Full Length 054 Reperfusion System		
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
Luer Integrity	Tested per ISO 80369-7:2021.	**PASS** All samples met the pre-determined acceptance criteria

Full Length 054 Reperfusion System		
Test	**Test Method**	**Results**
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:

No animal study was deemed necessary to demonstrate substantial equivalence to the predicate device.

Clinical Studies:

No clinical study was deemed necessary to demonstrate substantial equivalence to the predicate device.

Conclusion

The Route 92 Medical Full Length 054 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 performance testing demonstrates that the Route 92 Medical Full Length 054 Reperfusion System and Aspiration Tubing Set is substantially equivalent to the predicate device.