October 2, 2024

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

Re: K240529
Trade/Device Name: 8F Modified Sheath System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: August 29, 2024
Received: September 3, 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.

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)*
K240529

Device Name
8F Modified Sheath System

Indications for Use *(Describe)*
The 8F Modified Sheath System is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K240529 510(k) Summary

Sponsor:	Route 92 Medical, Inc. 155 Bovet Road, Suite 100 San Mateo, CA 94402
Contact:	Kirsten Valley 650-581-1179
Date Prepared:	September 30, 2024
Device Name:	8F Modified Sheath System
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature (Product Code QJP, 21 CFR 870.1250) Catheter, Percutaneous (Product Code DQY, 21 CFR 870.1250)
Legally Marketed Predicate Device:	Base Camp® Sheath System (K191717, Route 92 Medical)

Device Description

The 8F Modified 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 8F 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 8F Modified Sheath System is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Comparison to Predicate Device

The intended use, method of action, design, and materials of the 8F Modified Sheath System are substantially equivalent to the K191717 predicate device as shown in the following table.

Attribute	**Base Camp Sheath System, K191717 (Predicate Device)**	**8F Modified Sheath System, K240529 (Subject Device)**
Regulatory Classification	Catheter, Percutaneous, 21 CFR 870.1250	Catheter, Percutaneous, Neurovasculature, 21 CFR 870.1250

Attribute	Base Camp Sheath System, K191717 (Predicate Device)	8F Modified Sheath System, K240529 (Subject Device)
		Catheter, Percutaneous, 21 CFR 870.1250
Product Code	DQY, Catheter, Percutaneous	QJP, Catheter, Percutaneous, Neurovasculature DQY, Catheter, Percutaneous
Indications for Use	The Route 92 Medical Sheath is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The 8F Modified Sheath System is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.
Device Description	A single-lumen flexible, variable stiffness catheter with a hydrophilically-coated, shaft and a radiopaque marker band on the distal end.	Same as predicate device
User	Physicians trained in endovascular techniques	Same as predicate device
Anatomical Sites	Peripheral and neuro vasculature	Same as predicate device
Method of Action	Inserted at a vascular access point to provide access to the target site and once in place, provides a reinforcing conduit for other intravascular devices. Includes component(s) to facilitate percutaneous introduction and intravascular tracking of the device.	Same as predicate device
Lubricious Coating	Hydrophilic coating	Same as predicate device
How Supplied	Sterile, single-use	Same as predicate device
Packaging	Tyvek pouch, packaging card, and SBS carton	Same as predicate device
Sterilization	Ethylene oxide (EtO)	Same as predicate device
Shelf-Life	8 months	6 months
Accessories Included	Dilator, Navigating Catheter, and Rotating Hemostasis Valve	Same as predicate device
Dimensions		
Sheath		
Working Length(s)	90 cm	90 cm and 80 cm
Overall Length	96 cm	96 cm and 86 cm
Coating Length	8 cm	Same as predicate device
Inner Diameter	0.106”	Same as predicate device
Outer Diameter	0.122”	Same as predicate device

Attribute	Base Camp Sheath System, K191717 (Predicate Device)	8F Modified Sheath System, K240529 (Subject Device)
Tip Configuration/ Shape	Straight	Straight
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same as predicate device
Marker Band	Yes	Yes
Dilator		
Working Length(s)	103 cm	Same as predicate device
Overall Length	106 cm	Same as predicate device
Coating Length	15 cm	Same as predicate device
Inner Diameter (Distal)	0.040”	Same as predicate device
Inner Diameter (Proximal)	0.044”	Same as predicate device
Outer Diameter (Distal)	0.050”	Same as predicate device
Outer Diameter (Proximal)	0.102”	Same as predicate device
Tip Configuration/ Shape	Straight	Same as predicate device
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same as predicate device
Marker Band	Yes	Same as predicate device
Navigating Catheter		
Working Length(s)	113 cm	Same as predicate device
Overall Length	116 cm	Same as predicate device
Coating Length	40 cm	Same as predicate device
Inner Diameter	0.040”	Same as predicate device
Outer Diameter (Distal)	0.070”	Same as predicate device
Outer Diameter (Proximal)	0.104”	Same as predicate device

Attribute	Base Camp Sheath System, K191717 (Predicate Device)	8F Modified Sheath System, K240529 (Subject Device)
Tip Configuration/ Shape	Angled	Same as predicate device
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same as predicate device
Marker Band	Yes	Same as predicate device

Non-Clinical Testing

Biocompatibility Testing

The 8F Modified Sheath System is constructed using materials that are commonly used in the medical device industry. All patient contacting components have been evaluated for biocompatibility in accordance with ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

The Dilator, Navigating Catheter, and Rotating Hemostasis Valve are identical in materials and manufacturing to those previously cleared in K191717.

The 8F Modified Sheath is classified per ISO 10993-1 as externally communicating with limited circulating blood contact (<24 hours). A summary of the biocompatibility testing conducted on the 8F Modified Sheath is provided below.

Test	Results	Conclusions
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Sodium Chloride USP Solution and Sesame Oil)	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the test.	Test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Sodium Chloride USP Solution and Sesame Oil)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score were not greater than 1.0 for sodium chloride and sesame oil test article extracts.	Requirements of the ISO intracutaneous reactivity test have been met for the test article.
Acute Systemic Toxicity – ISO Acute Systemic Injection (Sodium Chloride USP Solution and Sesame Oil)	There was no mortality or evidence of systemic toxicity from the injected extracts. All animals treated were clinically normal throughout the study as compared to control mice.	Requirements of the ISO acute systemic injection test have been met for the test article.
Material Mediated Pyrogenicity	No single animal showed a temperature rise of 0.5ºC or more above its baseline temperature. The total rise of rabbits' temperatures during the 3-hour observation period was within acceptable USP requirements.	The test article met the requirements for the absence of pyrogens.

Test	Results	Conclusions
Cytotoxicity – ISO MEM Elution	No cytotoxicity or cell lysis was noted in any of the test wells. The test article extract met the requirements of the test as the grade was less than 2.	The test article is non-cytotoxic.
Hemocompatibility – ASTM Hemolysis	The test articles (via the direct contact method and indirect contact method) were both rated non-hemolytic.	The test article is considered non-hemolytic.
Hemocompatibility - Thrombogenicity: ASTM Partial Thromboplastin Time Assay	The test article average clotting time was not lower and was not statistically significant when compared to the negative control. The test article average clotting time was not lower and was not statistically significant when compared to the vehicle control.	The test article met the requirements of the test.
Hemocompatibility - Complement Activation Assay	The SC5b-9 concentration of the test article was not statistically higher than the activated normal human serum, the negative control, or the comparator test article.	The test article is a non-activator of the complement system.
Hemocompatibility - Thrombogenicity: ASTM Platelet/Leukocyte Count	The test article average platelet count was similar to the comparator test article, 80 to 120% of the vehicle control, and at least 30% above the positive control.	The test article met the requirements of the test.
Hemocompatibility - Thrombogenicity: Comparative Surface Assessment	40x magnification images taken of the subject device and predicate device show comparable surface morphologies.	The test article does not have any features that would increase thrombogenicity risk.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the 8F Medical Modified Sheath System is suitable for its intended use.

Test	Test Method	Results
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications.	**PASS** The pre-determined acceptance criteria were met.
Luer Integrity	Tested per ISO 80369-7:2016.	**PASS** The pre-determined acceptance criteria were met.

Test	Test Method	Results
Tensile Strength	The tensile strength of the catheter sections and bonds was tested.	**PASS** The pre-determined acceptance criteria were met.
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance.	**PASS** The pre-determined acceptance criteria were met.
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation.	**PASS** The pre-determined acceptance criteria were met.
Tip Flexibility	Test specimens were tested for tip flexibility.	**PASS** The pre-determined acceptance criteria were met.
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	**PASS** The pre-determined acceptance criteria were met.
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	**PASS** The pre-determined acceptance criteria were met.
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles in a vascular model.	**PASS** The pre-determined acceptance criteria were met.
Simulated Use Testing	Deliverability and compatibility with accessory devices were evaluated in a vascular model.	**PASS** The pre-determined acceptance criteria were met.
Static Burst Pressure Testing	Tested per ISO 10555-1:2013 Annex F.	**PASS** The pre-determined acceptance criteria were met.
Particulate Testing	The size and quantity of particulate matter generated during simulated use testing were determined.	**PASS** The pre-determined acceptance criteria were met.
Delivery/Retrieval Force Testing	The forces to deliver and retrieve the subject device in an anatomical model were measured.	**PASS**

Clinical Data and Animal Testing

Substantial equivalence was established based on non-clinical bench performance data. Clinical and animal testing data were not deemed necessary.

Sterilization

The 8F Modified Sheath System is sterilized using a validated EtO process with a sterility assurance level of $1x10^{-6}$ validated per the overkill method in accordance with ISO 11135, "Sterilization of Health-Care Products – Ethylene Oxide - Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices".

Substantial Equivalence

The 8F Modified Sheath System is substantially equivalent to the predicate Route 92 Medical's Base Camp Sheath System (K191717) in intended use, design, principles of operation, technology, and performance. The successful completion of biocompatibility testing and performance testing demonstrates that the 8F Modified Sheath System is safe and effective for its intended use and substantially equivalent to the predicate device.