



July 27, 2021

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

Re: K210635

Trade/Device Name: Route 92 Medical Full Length 088 Access System  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP  
Dated: June 28, 2021  
Received: June 29, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

## Indications for Use

510(k) Number (if known)

K210635

Device Name

Route 92 Medical Full Length 088 Access System

Indications for Use (Describe)

The Route 92 Medical Full Length 088 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

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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## K210635 510(k) Summary

<b>Sponsor:</b>	Route 92 Medical 155 Bovet Road, Suite 100 San Mateo, CA 94402 Phone: 650-581-1179
<b>Contact:</b>	Kirsten Valley
<b>Date Prepared:</b>	July 20, 2021
<b>Device Name:</b>	Route 92 Medical Full Length 088 Access System
<b>Common Name:</b>	Percutaneous Catheter
<b>Classification Name:</b>	Catheter, Percutaneous, Neurovasculature (Product Code QJP, 21 CFR 870.1250)
<b>Device Classification:</b>	Class II
<b>Predicate Device:</b>	Route 92 Medical 088 Access System, K201518

### Device Description

The Route 92 Medical Full Length 088 Access System is comprised of a Support Catheter and a Delivery Catheter. The Support Catheter is a single-lumen, variable stiffness catheter. The Delivery Catheter is a hubbed, single-lumen variable stiffness catheter. Both catheters are hydrophilically coated. The Route 92 Medical Full Length 088 Access System is intended for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system. The devices are provided sterile and non-pyrogenic and are intended for single use only.

### Indications for Use

The Route 92 Medical Full Length 088 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

### Comparison to the Predicate Device

The method of action, design, and materials of the Route 92 Medical Full Length 088 Access System are equivalent to the Predicate Device as shown in the following table.

<b>Attribute</b>	<b>Predicate Device</b> Route 92 Medical 088 Access System (K201518)	<b>Subject Device</b> Route 92 Medical Full Length 088 Access System (K210635)
Indications for Use	The Route 92 Medical 088 Access System, 143 cm, is indicated for use	The Route 92 Medical Full Length 088 Access System is indicated for

<b>Attribute</b>	<b>Predicate Device</b> Route 92 Medical 088 Access System (K201518)	<b>Subject Device</b> Route 92 Medical Full Length 088 Access System (K210635)
	with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.	use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.
Device Description	Sterile, single-use, variable stiffness, coil-reinforced catheter with proximal control wire	Sterile, single-use, variable stiffness, coil-reinforced catheter
Targeted population	Patients requiring use of a microcatheter in the neurovascular system	Same
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	100% ethylene oxide	Same
Shelf Life	8 months	Same
<b>Support Catheter</b>		
Inner Diameter	0.088"	Same
Outer Diameter	Distal: 0.101" Proximal: 0.105"	0.101"
Length	143 cm	132 cm and 125 cm
<b>Delivery Catheter</b>		
Inner Diameter	0.019"	Same
Outer Diameter	Distal: 0.080" Proximal: 0.062"	Same
Length	151 cm	Same

## Non-Clinical Testing

### Biocompatibility Testing

The Route 92 Medical Full Length 088 Access System is constructed using the same materials as the predicate device. 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 Route 92 Medical Full Length 088 Access System is classified per ISO 10993-1 as externally communicating with limited circulating blood contact (<24 hours). A summary of the biocompatibility testing is provided below.

<b>Test</b>	<b>Results</b>	<b>Conclusions</b>
Cytotoxicity – ISO MEM Elution	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test as grade was less than 2.	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Normal Saline 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.	The test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Normal Saline 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 was 1.0 or less for both 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 (Normal Saline and Sesame Oil)	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.	Requirements of the ISO acute systemic injection test have been met for the test article.
Pyrogen – Material Mediated Pyrogen (Normal Saline)	No single animal showed a temperature rise of 0.5°C or more above its baseline temperature.	The test article is non-pyrogenic.
Hemocompatibility- Complement Activation (SC5b-9)	The concentration of SC5b-9 in the test sample was lower than the concentration in the control sample.	The test article would not be expected to result in adverse effects in vivo.
Hemocompatibility – Partial Thromboplastin Time	The test article clotting time was not statistically different as compared to the control article.	The test article is considered to be a non-activator of the intrinsic coagulation pathway.
Hemocompatibility – ASTM Hemolysis	Both the test article in direct contact with blood and the test article extract were non-hemolytic.	The test article is considered non-hemolytic.

## Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical Full Length 088 Access System is suitable for its intended use.

<b>Test</b>	<b>Test Method</b>	<b>Results</b>
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications	<b>PASS</b> All samples met the pre-determined acceptance criteria
Luer Integrity	Tested per ISO 80369-7:2016	<b>PASS</b> All samples met the pre-determined acceptance criteria
Tensile Strength	The tensile strength of the catheter sections and bonds was tested	<b>PASS</b> All samples met the pre-determined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance	<b>PASS</b> All samples met the pre-determined acceptance criteria
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation	<b>PASS</b> All samples met the pre-determined acceptance criteria
Tip Flexibility	Test specimens were tested for tip flexibility	<b>PASS</b> All samples met the pre-determined acceptance criteria
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	<b>PASS</b> All samples met the pre-determined acceptance criteria
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	<b>PASS</b> All samples met the pre-determined acceptance criteria
Static Burst	Tested per ISO 10555-1:2013 Annex F.	<b>PASS</b> All samples met the pre-determined acceptance criteria
Dynamic Burst	Mechanical integrity was maintained up to the specified pressures	<b>PASS</b> 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.	<b>PASS</b> All samples met the pre-determined acceptance criteria

Test	Test Method	Results
Particulate Recovery	After multiple insertion and withdrawal cycles, the effluent water rinsed and flushed from the devices and model was tested per USP <788>. Particulates were characterized for size ranges $\geq 10 \mu\text{m}$ , $\geq 25 \mu\text{m}$ , $\geq 50 \mu\text{m}$ , $\geq 100 \mu\text{m}$ , $\geq 200 \mu\text{m}$ , $\geq 500 \mu\text{m}$ and $\geq 1000 \mu\text{m}$	<p style="text-align: center;"><b>PASS</b></p> <p style="text-align: center;">All samples met the pre-determined acceptance criteria</p>
Simulated Use Testing	Deliverability and compatibility with accessory devices were evaluated in a neurovascular model	<p style="text-align: center;"><b>PASS</b></p> <p style="text-align: center;">All samples met the pre-determined acceptance criteria</p>
Packaging Integrity	ISO 11607-1 Part 1 ISO 11607-2 Part 2	<p style="text-align: center;"><b>PASS</b></p> <p style="text-align: center;">All samples met the pre-determined acceptance criteria</p>

### Conclusions

The Route 92 Medical Full Length 088 Access System has the same intended use, the same technological characteristics and same method of action as the predicate device. Differences between the subject and predicate devices do not raise new concerns of safety and effectiveness of the device. The successful completion of biocompatibility testing and performance testing demonstrates that the Route 92 Medical Full Length 088 Access System is substantially equivalent to the predicate device.