U.S. FOOD & DRUG ADMINISTRATION

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

November 11, 2020

Re: K203043
Trade/Device Name: Route 92 Medical 070 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: October 2, 2020
Received: October 6, 2020

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203043

Device Name
Route 92 Medical 070 Access System

Indications for Use *(Describe)*
The Route 92 Medical 070 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.

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K203043 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:	November 10, 2020
Device Name:	Route 92 Medical 070 Access System
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter (Product Code QJP, 21 CFR 870.1250)
Predicate Device:	Route 92 Medical 088 Access System, K201518

Device Description

The Route 92 Medical 070 Access System is comprised of a Support Catheter and a Delivery Catheter. The distal portion of the Support Catheter is a single-lumen, variable stiffness catheter. Like the predicate device, the proximal portion is a stainless-steel control wire. The Delivery Catheter is a hubbed, single-lumen variable stiffness catheter. Both catheters are hydrophilically coated. The Route 92 Medical 070 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 070 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 070 Access System are equivalent to the Predicate Device as shown in the following table.

Attribute	Predicate Device Route 92 Medical 088 Access System (K201518)	Subject Device Route 92 Medical 070 Access System
Indications for Use	The Route 92 Medical 088 Access System, 143 cm, 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.	The Route 92 Medical 070 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.
Device Description	Sterile, single-use, variable stiffness, coil-reinforced catheter with proximal control wire	Same
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
Support Catheter		
Inner Diameter	0.088”	0.070”
Outer Diameter	Distal: 0.101” Proximal: 0.105”	Distal: 0.082” Proximal: 0.087”
Length	143 cm	142 cm
Delivery Catheter		
Inner Diameter	0.019”	Same
Outer Diameter	Distal: 0.080” Proximal: 0.062”	0.062”
Length	151 cm	Same

Non-Clinical Testing

Biocompatibility Testing

The Route 92 Medical 070 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 070 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.

Test	Conclusions
Cytotoxicity – ISO MEM Elution	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Normal Saline and Sesame Oil)	The test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Normal Saline and Sesame Oil)	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)	Requirements of the ISO acute systemic injection test have been met for the test article.
Pyrogen – Material Mediated Pyrogen (Normal Saline)	The test article is non-pyrogenic.
Hemocompatibility – Complement Activation (SC5b-9)	The test article would not be expected to result in adverse effects in vivo.
Hemocompatibility – Partial Thromboplastin Time	The test article is considered to be a non-activator of the intrinsic coagulation pathway.
Hemocompatibility – ASTM Hemolysis	The test article is considered non-hemolytic.
Hemocompatibility – Thromboresistance	The test articles have similar thromboresistance characteristics as the control devices.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical 070 Access System is suitable for its intended use.

Test	Test Method	Results
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications	**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

Test	Test Method	Results
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 / Static Burst	Tested per ISO 10555-1:2013 Annex C.	**PASS** All samples met the pre-determined acceptance criteria
Dynamic Burst	Mechanical integrity was maintained up to the specified pressures	**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
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 ≥10 µm, ≥25 µm, ≥50 µm, ≥100 µm, ≥200 µm, ≥500 µm and ≥1000 µm	**PASS** All samples met the pre-determined acceptance criteria
Simulated Use Testing	Deliverability and compatibility with accessory devices was evaluated in a neurovascular model	**PASS** All samples met the pre-determined acceptance criteria

Substantial Equivalence

The Route 92 Medical 070 Access System has the same intended use, the same technological characteristics and same method of action as the predicate device. The successful completion of

biocompatibility testing and performance testing demonstrates that the Route 92 Medical 070 Access System is substantially equivalent to the predicate device.