May 23, 2018

Route 92 Medical, Inc.
Kirsten Valley
Senior VP QA/RA/CA
1700 South El Camino Real, Suite 206
San Mateo, California 94402

Re: K180201
Trade/Device Name: Route 92 Medical Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 23, 2018
Received: April 24, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K180201

Device Name
Route 92 Medical Access System

Indications for Use *(Describe)*
The Route 92 Medical 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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K180201

510(K) SUMMARY

510(k) Summary

Sponsor: Route 92 Medical
1700 S. El Camino Real, Suite 206
San Mateo, CA 94022
Phone: 650-581-1179
Fax: 650-343-5827

Contact: Kirsten Valley

Date Prepared: May 3, 2018

Device Name: Route 92 Medical Access System

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter (Product Code DQY, 21 CFR 870.1250)

Legally Marketed Predicate Device: MIVI Mi-EXT Catheter (K163233)

Device Description

The Route 92 Medical Access System is comprised of an Access Catheter and a Delivery Catheter. The distal portion of the Access 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 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 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 Predicate Device

The method of action, design, and materials of the Route 92 Medical Access System are equivalent to the MIVI Mi-EXT Catheter as shown in the following table.

Attribute	Predicate MIVI Mi-EXT Catheter (K163233)	Subject Route 92 Medical Access System
Indications for Use	The MIVI 6F Guide Catheter is indicated for use with compatible guide catheters	The Route 92 Medical Access System is indicated for use with compatible

Attribute	Predicate MIVI Mi-EXT Catheter (K163233)	Subject Route 92 Medical Access System
	in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.	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 as predicate device.
Targeted population	Patients requiring use of a microcatheter in the peripheral, coronary or neurovascular systems	Patients requiring use of a microcatheter in the neurovascular system
User	Physicians trained in interventional techniques	Physicians trained in neurovascular interventional techniques
Anatomical Sites	Peripheral, coronary or neurovascular systems	Neurovasculature only
Method of Action	Delivered through a guide catheter with support of a microcatheter/delivery catheter, the device provides a lumen for the introduction of microcatheters.	Same as predicate device
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same as predicate device
Access Catheter		
Inner Diameter	0.069”	0.070” (minimum)
Outer Diameter	Distal: 0.081” Proximal: 0.087”	Distal: 0.082” Proximal: 0.087”
Length	140 – 153cm	136cm
Delivery Catheter		
Inner Diameter	N/A	0.019”
Outer Diameter	N/A	0.062”
Length	N/A	150cm

Non-Clinical Testing

Biocompatibility Testing

The Route 92 Medical Access 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 Route 92 Medical 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	Results	Conclusions
Cytotoxicity – ISO MEM Elution	Grade 0 at 24, 48, 72 ± 4 hrs	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Normal Saline and Sesame Oil)	Clinical Observations: none of the animals showed abnormal clinical signs during the test period. Main Test Results: Negative Control, grade =0 Normal Saline, grade = 0 Sesame Oil, grade = 0	Test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Normal Saline and Sesame Oil)	Dermal observations: Comparative Results Mean Test-Mean Control (Normal Saline) = 0 Mean Test-Mean Control (Sesame Oil) = 0.1 Differences between mean test and control scores were less than 1.0	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)	None of the test article extract treated animals were observed with clinical signs consistent with toxicity. Body weight changes were within acceptable parameters.	Requirements of the ISO acute systemic injection test have been met for the test article.
Pyrogen – Material Mediated Pyrogen (Normal Saline)	During the 3-hr observation period, none of the rabbits administered with the text article extract had a temperature rise ≥ 0.5°C at the required observation time points. The response did not exceed the USP limits and meets the requirements for this test.	The test article is non-pyrogenic.
Hemocompatibility – Complement Activation (C3a & SC5b-9)	When compared to a legally US-marketed device, the minimal increase in complement activation noted in the test article would not be expected to result in adverse effects in vivo.	The test article would not be expected to result in adverse effects in vivo.
Hemocompatibility – Partial Thromboplastin Time	The PPT of the test article was 100% of the negative control.	The test article is considered to be a non-activator of the intrinsic coagulation pathway and passes the test.
Hemocompatibility – ASTM Hemolysis	Blank corrected hemolytic index above the negative control: Direct Method: 0.0% Extract Method: 0.3%	The test article is considered non-hemolytic.
Hemocompatibility – Thromboresistance	All test animals survived the general anesthesia and study observation interval without test article related complications.	The test devices appear to have similar thromboresistance characteristics as the

	The combined data of blood test reports, pre- and post-implant weight differences, and the patency and thrombus scores were not subjectively different between the test and control articles.	control devices.
Genotoxicity – ISO Bacterial Mutagenicity Test – Ames Assay (Normal Saline and Polyethylene Glycol)	The test article did not induce substantial increases in reversion rates of the type that are associated with mutagenesis and no substantial test article toxicity was noted that may have interfered with the ability of the test system to detect mutagens.	The test article is considered non-mutagenic.
Genotoxicity – ISO In Vitro Mouse Lymphoma (Normal Saline and Polyethylene Glycol)	The test article did not cause notable changes in the typical growth pattern of the L5178Y cells in suspension culture during the growth and expression period. The cloning efficiencies of these preparations were within normal limits.	The test article is considered to be non-mutagenic and non-clastogenic.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical 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
Luer Integrity	Tested per ISO 80369-7:2016	**PASS** All samples met the pre-determined acceptance criteria
RHV Sealing	RHV sealing around the catheter shafts was tested	**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

Test	Test Method	Results
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
Flow	Contrast media flow rates were measured and found to be equivalent to predicate devices	**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>.	**PASS** All samples met the pre-determined acceptance criteria
Corrosion Resistance	Tested per ISO 10555-1:2013 Annex A.	**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
Packaging Integrity	ISO 11607-1 Part 1 ISO 11607-2 Part 2	**PASS** All samples met the pre-determined acceptance criteria

Test	Test Method	Results
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy	**PASS** All samples met the pre-determined acceptance criteria

Substantial Equivalence

The Route 92 Medical Access System has the same intended use, the same technological characteristics and same method of action as the predicate MIVI Mi-EXT Catheter. The successful completion of biocompatibility testing and performance testing demonstrates that the Route 92 Medical Access System is substantially equivalent to MIVI Mi-EXT Catheter.