



March 21, 2019

Route 92 Medical Inc.
Kathy Tansey
Senior Director of Regulatory Affairs and Quality Assurance
1700 South El Camino Real, Suite 206
San Mateo, California 94402

Re: K190431
Trade/Device Name: Route 92 Medical Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 20, 2019
Received: February 22, 2019

Dear Kathy Tansey:

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.

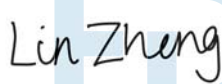
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,


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Date: 2019.03.21
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for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190431

Device Name

Route 92 Medical Delivery Catheter

Indications for Use (Describe)

The Route 92 Medical Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters 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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K190431

510(k) Summary

510(k) Summary

Sponsor: Route 92 Medical
1700 S. El Camino Real, Suite 206
San Mateo, CA 94022
Phone: 408-391-6536
Fax: 650-343-5827

Contact: Kathy Tansey

Date Prepared: March 18, 2019

Device Name: Route 92 Medical Delivery Catheter

Common Name: Percutaneous Catheter

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

Legally Marketed Predicate Device: Route 92 Medical Delivery Catheter (K182512)

Device Description

The modified Route 92 Medical Delivery Catheter is a single-lumen, variable stiffness, hydrophilically coated catheter with a flexible tapered tip. The tapered tip is delineated by two radiopaque markers. On the proximal end is a luer hub for guidewire introduction and fluid or contrast injection. The devices are provided sterile and non-pyrogenic and are intended for single use only. During use, a standard neurovascular guidewire may be inserted through the Delivery Catheter. The Delivery Catheter is inserted through a compatible catheter. The Delivery Catheter and compatible catheter are advanced to the targeted location under fluoroscopy using standard endovascular techniques.

Indications for Use

The Route 92 Medical Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.

Comparison to Predicate Device

The method of action, design, and materials of the modified Route 92 Medical Delivery Catheter are equivalent to the cleared Route 92 Medical Delivery Catheter as shown in the following table.

Attribute	Cleared Route 92 Medical Delivery Catheter (K182512)	Modified Route 92 Medical Delivery Catheter
Indications for Use	The Route 92 Medical Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and	Same as cleared device

Attribute	Cleared Route 92 Medical Delivery Catheter (K182512)	Modified Route 92 Medical Delivery Catheter
	guidance of catheters into a selected blood vessel in the neurovascular system.	
Device Description	The Delivery Catheter is a sterile, single-use, single-lumen, hydrophilically coated, variable stiffness catheter with a flexible, tapered tip.	Same as cleared device
User	Physicians trained in neurovascular interventional techniques	Same as cleared device
Anatomical Sites	Neurovasculature only	Same as cleared device
Materials	Biocompatible polymers and metals commonly used in the manufacture of medical devices Catheter Shaft: stainless steel and varying durometers of Pebax Luer: polycarbonate Marker bands: Tungsten/Pebax	Same as cleared device
Coating	Hydrophilic coating	Same as cleared device
Inner Diameter	0.019”	Same as cleared device
Outer Diameter	0.062”	Same as cleared device
Working Length	143 cm	151 cm
Length of Polymer Section (non-hypotube section)	38 cm	71 cm
Hydrophilic Coating Length	48.5 cm	90 cm
Steam Shapeable Tip	Not discussed in labeling	Steam shaping added to labeling
Packaging	The shelf carton contains two (2) sterile pouches, each containing a Delivery Catheter and one (1) Directions for Use (DFU).	The shelf carton contains one (1) sterile pouch containing a Delivery Catheter and one (1) Directions for Use (DFU).
Sterilization	Ethylene Oxide	Same as cleared device

Performance Testing – Bench

The successful completion of the performance testing listed in the following table demonstrates that the modified Route 92 Medical Delivery Catheter is suitable for its intended use.

Test	Test Method	Results
Package Integrity after Aging and Distribution	The test specimens were subjected to EO sterilization and environmental conditioning, mechanical transit challenges, visual inspection and bubble leak test and peel test per ASTM F2096 and ASTM F88.	PASS All samples met the pre-determined acceptance criteria
Label Integrity after Aging and Distribution	The test specimens were subjected to EO sterilization and climatic conditioning per ASTM D4169.	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
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
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
Catheter Burst Pressure (Static & Dynamic)	Tested per ISO 10555-1:2013 Annex F.	PASS All samples met the pre-determined acceptance criteria
Catheter Flow Rate	Tested per ISO 10555-1:2013 Annex E.	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

Test	Test Method	Results
Packaging Integrity	ISO 11607-1 Part 1 ISO 11607-2 Part 2	PASS All samples met the pre-determined acceptance criteria

Biocompatibility

Biocompatibility evaluations were not conducted using the modified Route 92 Medical Delivery Catheter because the materials of construction and manufacturing processes have not changed from the predicate device. Therefore, the biocompatibility evaluations performed using the predicate Route 92 Medical Delivery Catheter (K182512) can also support the biocompatibility profile of the subject device.

Substantial Equivalence

The modified Route 92 Medical Delivery Catheter has the same intended use, similar technological characteristics and same method of action as the predicate Route 92 Medical Delivery Catheter (K182512). The successful completion of performance testing demonstrates that the modified Route 92 Medical Delivery Catheter is substantially equivalent to the predicate Route 92 Medical Delivery Catheter.