March 18, 2020

Reflow Medical
Krystal Santiago
Director RA/QA
208 Avenida Fabricante #100
San Clemente, California 92672

Re: K200094
Trade/Device Name: speX LP Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 26, 2020
Received: February 27, 2020

Dear Krystal Santiago:

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,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular 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)*

K200094

Device Name
speX LP Support Catheter

Indications for Use *(Describe)*
The speX LP Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

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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510(K) SUMMARY

Contact	ReFlow Medical, Inc. 208 Avenida Fabricante #100 San Clemente, CA 92672 Contact person: Krystal Santiago Phone: (949) 481-0399
Date Prepared	January 15, 2020
Device	Name of the device: speX LP Support Catheter Common of usual name: Support Catheter Classification name: Percutaneous Catheter Regulatory Class: 2 Product Code: DQY
Legally marketed device to which your firm is claiming equivalence	speX Support Catheter (K173662) This predicate has not been subject to a design-related recall
Description of the device	The speX LP Support Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral and/or coronary vasculature. The device consists of a support catheter body with a luer end. The through-lumen of the device can serve as a conduit for the delivery of diagnostic and therapeutic agents
Intended use of the device	The speX LP Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

Summary of the technological characteristics of your device compared to the predicate device

The speX LP Support Catheter is nearly identical to the speX Support Catheter previously cleared (K173662) version of the device.

The subject and predicate devices are based on the following identical technological elements:

- all delivered to the target site using an over-the-wire percutaneous technique
- all have a through lumen to allow passage and exchange of guidewires
- all have a smooth inner lumen to provide reduced friction for guidewire movement
- all have a polymer catheter shaft with specific geometry to control the torque and push movements associated with lesion crossing

The following technological differences exist between the subject and predicate devices:

- The distal tip of the speX LP support catheter has been modified to replace the one (1) radiopaque marker with three (3) lower profile markers.

A brief discussion of the nonclinical tests submitted
The following performance data were provided in support of the substantial equivalence. • Simulated Use Testing The speX LP Support Catheter met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the speX LP Support Catheter was found to have a safety and effectiveness profile that is similar to the predicate device.
Conclusions
The design testing performed for the speX LP Support Catheter demonstrated that the performance of the device is equal to the legally marketed predicate devices.