December 20, 2017

ReFlow Medical, Inc.
Ms. Rebecca Pine
Vice President, Regulatory, Quality and Clinical Affairs
1003 Calle Sombra
San Clemente, California 92673

Re: K173662
Trade/Device Name: speX Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 28, 2017
Received: November 29, 2017

Dear Ms. Pine:

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,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173662

Device Name
speX Support Catheter

Indications for Use *(Describe)*
The speX 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

I. SUBMITTER

ReFlow Medical, Inc.
1003 Calle Sombra
San Clemente, CA 92673

Contact person: Rebecca K Pine
Phone: (760) 809-5178
Fax: (760) 290.3216
Date prepared: March 31, 2017

II. DEVICE

Name of the device: speX Support Catheter
Common of usual name: Support Catheter
Classification name: Percutaneous Catheter
Regulatory Class: 2
Product Code: DQY

III. PREDICATE DEVICE

speX Support Catheter (K141649)
This predicate has not been subject to a design-related recall
The Wingman 14 Crossing Catheter (K132420) and Wingman 18 Crossing Catheter (K151880) were used as reference predicates in this submission

IV. DEVICE DESCRIPTION

The speX 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.

V. INDICATIONS FOR USE

The speX 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the modified speX Support Catheter are highly analogous to the technological characteristics of the speX Support Catheter previously cleared (K141649) version of the device.

At a high level, the subject and predicate devices are based on the following same 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 speX Support Catheter incorporates a gold plating within the shapeable region at the distal end of the catheter for increased radiovisibility
- Additional product diameters have been incorporated into the product family to facilitate use with .014" and .018" guidewires.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Simulated Use Testing
- Component/Assembly Integrity Testing
- Corrosion Resistance Testing
- Lubricity Testing

The modified speX Support Catheter met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the modified speX Support Catheter was found to be substantially equivalent to the predicate device.

VIII. CONCLUSIONS

The design testing performed for the speX Support Catheter demonstrated that the performance of the device is substantially equivalent to the legally marketed predicate devices.