May 28, 2021

Reflow Medical
Jeff Vander Hoek
Director RA/QA
208 Avenida Fabricante #100
San Clemente, California 92672

Re: K210188
Trade/Device Name: coraCross
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 22, 2021
Received: January 25, 2021

Dear Jeff Vander Hoek:

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,

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210188

Device Name
coraCross

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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	February 17, 2021
Device	Name of the device: coraCross Catheter Common of usual name: Crossing Catheter Classification name: Percutaneous Catheter Regulatory Class: 2 Product Code: DQY
Legally marketed device to which your firm is claiming equivalence	Wingman 14C Crossing Catheter (K190393) This predicate has not been subject to a design-related recall Reference Devices: speX LP 14 Support Catheter (K200094) coraForce/ coraFlex (K201811) Wingman 18C (K160848)
Description of the device	The coraCross 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, with a concealed radiopaque beveled guide-tip, and activating handle. The through-lumen of the device can serve as a conduit for the delivery of diagnostic contrast.
Intended use of the device	The coraCross Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral and/or coronary 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 contrast.
Summary of the technological characteristics of your device compared to the predicate device	
The coraCross Catheter is nearly identical to the Wingman 14C previously cleared (K190393) 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 inner catheter of the device is leveraged from the Spex LP catheter (K200094)
- The beveled tip attachment method
- Hydrophilic Coating Length

A brief discussion of the nonclinical tests submitted

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

- Simulated Use Testing
- Leak Testing
- Kink Resistance
- Corrosion Testing
- Bond Testing
- Component Integrity Testing
- Particulate Testing
- Torque Testing
- Catheter Flow/Burst Testing
- Lubricity Testing

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

Conclusions

The design testing performed for the coraCross Catheter demonstrated equivalence to the legally marketed predicate device.