February 20, 2020

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

Re: K193596
Trade/Device Name: Wingman 14, Wingman 14C, Wingman 18, Wingman 35
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, DQY
Dated: December 20, 2019
Received: December 23, 2019

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

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)*
K193596

Device Name
Wingman Crossing Catheters

Indications for Use *(Describe)*
The Wingman Crossing Catheters (14/14C/18/35) are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices, including facilitation of the intraluminal placement of diagnostic/ interventional devices beyond peripheral stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents.

The Wingman 14C Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents.

The Wingman 14, 18, & 35 Crossing Catheter is contraindicated for use in the coronary and cerebral vasculature. The Wingman 14C Crossing Catheter is contraindicated for use in the cerebral vasculature.

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

Submitter	Reflow Medical, Inc. 208 Avenida Fabricante #100 San Clemente, CA 92672 Contact person: Krystal Santiago Phone: (310) 707.5882
Date Prepared	February 8, 2020
Device	Name of the device: Wingman Crossing Catheter Common of usual name: Percutaneous Catheter Classification name: Percutaneous Catheter Regulatory Class: 2 Product Code: PDU, DQY
Legally marketed device to which your firm is claiming equivalence	Predicate Device: Medtronic Viance Crossing Catheter K120533 Reference Devices: Wingman Crossing Catheter K132420 (Wingman 14) K190393 (Wingman 14C) K160848 (Wingman 18) K173661 (Wingman 35)
Description of the device	The Wingman Crossing Catheter (14/18/35) is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The Wingman Crossing Catheter (14C) is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the coronary vasculature and peripheral 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 and therapeutic agents.
Intended use of the device	The Wingman Crossing Catheters (14/14C/18/35) are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices, including facilitation of the intraluminal placement of diagnostic/ interventional devices beyond peripheral stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents. The Wingman 14C Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents. The Wingman 14/18/35 Crossing Catheters are contraindicated for use in the coronary and cerebral vasculature. The Wingman 14C Crossing Catheter is contraindicated for use in the cerebral vasculature.

Summary of the technological characteristics of your device compared to the predicate device	
The technological characteristics of the subject Wingman Crossing Catheter are identical to the technological characteristics of the Wingman Crossing Catheter previously cleared K132420 (Wingman 14), K190393 (Wingman 14C), K160848 (Wingman 18), K173661 (Wingman 35) version of the device. The Wingman device is clinically substantially equivalent to the Medtronic Viance Crossing Catheter (K120533). 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 • all use a specialized distal tip to facilitate crossing of the lesion The following technological differences exist between the subject and predicate devices: • The subject Wingman device has a slightly differing distal tip configuration in comparison to the Medtronic Viance catheter, however both tip designs have been shown to achieve the same clinical outcomes. • The subject Wingman Crossing Catheters are available in a wider product range encompassing 0.014-0.035" guidewire compatibility vs the standard 0.014" Medtronic Viance Catheter.	
A brief discussion of the nonclinical tests submitted	
No additional nonclinical tests are submitted.	
A brief discussion of the clinical data submitted	
This was a non-randomized, prospective, multi-center, single-arm study designed to evaluate the safety and effectiveness of the Wingman device to cross CTOs in infrainguinal arteries. The study was conducted both in the United States and outside the United States in Germany and Austria. At baseline, the mean age of the study subjects was 71.4 ± 9.3 years, and 65.9% (56/85) was male. The mean body mass index (BMI) was 27.7 ± 5.3. A history of smoking was elicited in 76.5% (65/85) of subjects, and 30.6% (26/85) diabetic. A history of peripheral interventions was reported in 63.5% (54/85) of subjects and the most common Rutherford Category was 3, present in 70.6% (60/85) of subjects. Among 85 subjects with 86 CTO lesions that could not be traversed with standard guidewires and techniques, 77 (89.5%) were successfully crossed with the Wingman study device. The lower 95% confidence limit for successful CTO crossing (the primary effectiveness endpoint) was 82.5%, meeting the primary effectiveness endpoint. These results were achieved with a 4.8% (4/83) 30-day rate of MAE, perforation, embolization, or dissection; the primary safety endpoint. The upper 95% confidence limit for the primary safety endpoint was 10.7%, meeting the primary safety endpoint. Both the primary endpoints were met, suggesting that the Wingman study device was safe and effective for crossing CTO lesions unable to be traversed with standard guidewires and techniques.	
Conclusions	
The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed devices identified.	